108TH CONGRESS } HOUSE OF REPRESENTATIVES { REPT. 108–74
1st Session } { Part 1

MEDICARE REGULATORY AND CONTRACTING REFORM ACT OF 2003

APRIL 11, 2003.—Ordered to be printed

Mr. THOMAS, from the Committee on Ways and Means, submitted the following

R E P O R T

together with

DISSENTING VIEWS

[To accompany H.R. 810]

[Including cost estimate of the Congressional Budget Office]

The Committee on Ways and Means, to whom was referred the bill (H.R. 810) to amend title XVIII of the Social Security Act to provide regulatory relief and contracting flexibility under the Medicare Program, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

CONTENTS

19–006

The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE; AMENDMENTS TO SOCIAL SECURITY ACT; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Medicare Regulatory and Contracting Reform Act of 2003".

(b) AMENDMENTS TO SOCIAL SECURITY ACT.—Except as otherwise specifically provided, whenever in this Act an amendment is expressed in terms of an amendment to or repeal of a section or other provision, the reference shall be considered to be made to that section or other provision of the Social Security Act.

(c) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

SEC. 2. FINDINGS AND CONSTRUCTION.

(a) FINDINGS.—Congress finds the following:

(1) The overwhelming majority of providers of services and suppliers in the United States are law-abiding persons who provide important health care services to patients each day.

(2) The Secretary of Health and Human Services should work to streamline paperwork requirements under the medicare program and communicate clearer instructions to providers of services and suppliers so that they may spend more time caring for patients.

(b) CONSTRUCTION.—Nothing in this Act shall be construed—

(1) to compromise or affect existing legal remedies for addressing fraud or abuse, whether it be criminal prosecution, civil enforcement, or administrative remedies, including under sections 3729 through 3733 of title 31, United States Code (known as the False Claims Act); or

(2) to prevent or impede the Department of Health and Human Services in any way from its ongoing efforts to eliminate waste, fraud, and abuse in the medicare program.

Furthermore, the consolidation of medicare administrative contracting set forth in this Act does not constitute consolidation of the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund or reflect any position on that issue.

SEC. 3. DEFINITIONS.

(a) USE OF TERM SUPPLIER IN MEDICARE.—Section 1861 (42 U.S.C. 1395x) is amended by inserting after subsection (c) the following new subsection:

"Supplier

"(d) The term 'supplier' means, unless the context otherwise requires, a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services under this title.".

(b) OTHER TERMS USED IN ACT.—In this Act:

(1) BIPA.—The term "BIPA" means the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, as enacted into law by section 1(a)(6) of Public Law 106–554.

(2) SECRETARY.—The term "Secretary" means the Secretary of Health and Human Services.

TITLE I—REGULATORY REFORM

SEC. 101. ISSUANCE OF REGULATIONS.

(a) LIMITATIONS ON NEW MATTER IN FINAL REGULATIONS.—Section 1871(a) (42 U.S.C. 1395hh(a)) is amended by adding at the end the following new paragraph:

"(3) If the Secretary publishes a final regulation that includes a provision that is not a logical outgrowth of a previously published notice of proposed rulemaking or interim final rule, such provision shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to final regulations published on or after the date of the enactment of this Act.

SEC. 102. COMPLIANCE WITH CHANGES IN REGULATIONS AND POLICIES.

(a) NO RETROACTIVE APPLICATION OF SUBSTANTIVE CHANGES.—

(1) IN GENERAL.—Section 1871 (42 U.S.C. 1395hh), as amended by section 101(a), is amended by adding at the end the following new subsection:

"(d)(1)(A) A substantive change in regulations, manual instructions, interpretative rules, statements of policy, or guidelines of general applicability under this title shall not be applied (by extrapolation or otherwise) retroactively to items and services furnished before the effective date of the change, unless the Secretary determines that—

"(i) such retroactive application is necessary to comply with statutory requirements; or

"(ii) failure to apply the change retroactively would be contrary to the public interest.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to substantive changes issued on or after the date of the enactment of this Act.

(b) TIMELINE FOR COMPLIANCE WITH SUBSTANTIVE CHANGES AFTER NOTICE.—

(1) IN GENERAL.—Section 1871(d)(1), as added by subsection (a), is amended by adding at the end the following:

"(B)(i) Except as provided in clause (ii), a substantive change referred to in subparagraph (A) shall not become effective before the end of the 30-day period that begins on the date that the Secretary has issued or published, as the case may be, the substantive change.

"(ii) The Secretary may provide for such a substantive change to take effect on a date that precedes the end of the 30-day period under clause (i) if the Secretary finds that waiver of such 30-day period is necessary to comply with statutory requirements or that the application of such 30-day period is contrary to the public interest. If the Secretary provides for an earlier effective date pursuant to this clause, the Secretary shall include in the issuance or publication of the substantive change a finding described in the first sentence, and a brief statement of the reasons for such finding.

"(C) No action shall be taken against a provider of services or supplier with respect to noncompliance with such a substantive change for items and services furnished before the effective date of such a change.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to compliance actions undertaken on or after the date of the enactment of this Act.

(c) RELIANCE ON GUIDANCE.—

(1) IN GENERAL.—Section 1871(d), as added by subsection (a), is further amended by adding at the end the following new paragraph:

"(2)(A) If—

"(i) a provider of services or supplier follows the written guidance (which may be transmitted electronically) provided by the Secretary or by a medicare contractor (as defined in section 1889(g)) acting within the scope of the contractor's contract authority, with respect to the furnishing of items or services and submission of a claim for benefits for such items or services with respect to such provider or supplier;

"(ii) the Secretary determines that the provider of services or supplier has accurately presented the circumstances relating to such items, services, and claim to the contractor in writing; and

"(iii) the guidance was in error;

the provider of services or supplier shall not be subject to any sanction (including any penalty or requirement for repayment of any amount) if the provider of services or supplier reasonably relied on such guidance.

"(B) Subparagraph (A) shall not be construed as preventing the recoupment or repayment (without any additional penalty) relating to an overpayment insofar as the overpayment was solely the result of a clerical or technical operational error.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on the date of the enactment of this Act but shall not apply to any sanction for which notice was provided on or before the date of the enactment of this Act.

SEC. 103. REPORTS AND STUDIES RELATING TO REGULATORY REFORM.

(a) GAO STUDY ON ADVISORY OPINION AUTHORITY.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study to determine the feasibility and appropriateness of establishing in the Secretary authority to provide legally binding advisory opinions on appropriate interpretation and application of regulations to carry out the medicare program under title XVIII of the Social Security Act. Such study shall examine the appropriate timeframe for issuing such advisory opinions, as well as the need for additional staff and funding to provide such opinions.

(2) REPORT.—The Comptroller General shall submit to Congress a report on the study conducted under paragraph (1) by not later than one year after the date of the enactment of this Act.

(b) REPORT ON LEGAL AND REGULATORY INCONSISTENCIES.—Section 1871 (42 U.S.C. 1395hh), as amended by section 2(a), is amended by adding at the end the following new subsection:

"(e)(1) Not later than 2 years after the date of the enactment of this subsection, and every 2 years thereafter, the Secretary shall submit to Congress a report with respect to the administration of this title and areas of inconsistency or conflict among the various provisions under law and regulation.

"(2) In preparing a report under paragraph (1), the Secretary shall collect—

"(A) information from individuals entitled to benefits under part A or enrolled under part B, or both, providers of services, and suppliers and from the Medicare Beneficiary Ombudsman and the Medicare Provider Ombudsman with respect to such areas of inconsistency and conflict; and

"(B) information from medicare contractors that tracks the nature of written and telephone inquiries.

"(3) A report under paragraph (1) shall include a description of efforts by the Secretary to reduce such inconsistency or conflicts, and recommendations for legislation or administrative action that the Secretary determines appropriate to further reduce such inconsistency or conflicts.".

TITLE II—CONTRACTING REFORM

SEC. 201. INCREASED FLEXIBILITY IN MEDICARE ADMINISTRATION.

(a) CONSOLIDATION AND FLEXIBILITY IN MEDICARE ADMINISTRATION.—

(1) IN GENERAL.—Title XVIII is amended by inserting after section 1874 the following new section:

"CONTRACTS WITH MEDICARE ADMINISTRATIVE CONTRACTORS

"SEC. 1874A. (a) AUTHORITY.—

"(1) AUTHORITY TO ENTER INTO CONTRACTS.—The Secretary may enter into contracts with any eligible entity to serve as a medicare administrative contractor with respect to the performance of any or all of the functions described in paragraph (4) or parts of those functions (or, to the extent provided in a contract, to secure performance thereof by other entities).

"(2) ELIGIBILITY OF ENTITIES.—An entity is eligible to enter into a contract with respect to the performance of a particular function described in paragraph (4) only if—

"(A) the entity has demonstrated capability to carry out such function;

"(B) the entity complies with such conflict of interest standards as are generally applicable to Federal acquisition and procurement;

"(C) the entity has sufficient assets to financially support the performance of such function; and

"(D) the entity meets such other requirements as the Secretary may impose.

"(3) MEDICARE ADMINISTRATIVE CONTRACTOR DEFINED.—For purposes of this title and title XI—

"(A) IN GENERAL.—The term 'medicare administrative contractor' means an agency, organization, or other person with a contract under this section.

"(B) APPROPRIATE MEDICARE ADMINISTRATIVE CONTRACTOR.—With respect to the performance of a particular function in relation to an individual entitled to benefits under part A or enrolled under part B, or both, a specific provider of services or supplier (or class of such providers of services or suppliers), the 'appropriate' medicare administrative contractor is the medicare administrative contractor that has a contract under this section with respect to the performance of that function in relation to that individual, provider of services or supplier or class of provider of services or supplier.

"(4) FUNCTIONS DESCRIBED.—The functions referred to in paragraphs (1) and (2) are payment functions, provider services functions, and functions relating to services furnished to individuals entitled to benefits under part A or enrolled under part B, or both, as follows:

"(A) DETERMINATION OF PAYMENT AMOUNTS.—Determining (subject to the provisions of section 1878 and to such review by the Secretary as may be provided for by the contracts) the amount of the payments required pursuant to this title to be made to providers of services, suppliers and individuals.

"(B) MAKING PAYMENTS.—Making payments described in subparagraph (A) (including receipt, disbursement, and accounting for funds in making such payments).

"(C) BENEFICIARY EDUCATION AND ASSISTANCE.—Providing education and outreach to individuals entitled to benefits under part A or enrolled under part B, or both, and providing assistance to those individuals with specific issues, concerns or problems.

"(D) PROVIDER CONSULTATIVE SERVICES.—Providing consultative services to institutions, agencies, and other persons to enable them to establish and maintain fiscal records necessary for purposes of this title and otherwise to qualify as providers of services or suppliers.

"(E) COMMUNICATION WITH PROVIDERS.—Communicating to providers of services and suppliers any information or instructions furnished to the medicare administrative contractor by the Secretary, and facilitating communication between such providers and suppliers and the Secretary.

"(F) PROVIDER EDUCATION AND TECHNICAL ASSISTANCE.—Performing the functions relating to provider education, training, and technical assistance.

"(G) ADDITIONAL FUNCTIONS.—Performing such other functions as are necessary to carry out the purposes of this title.

"(5) RELATIONSHIP TO MIP CONTRACTS.—

"(A) NONDUPLICATION OF DUTIES.—In entering into contracts under this section, the Secretary shall assure that functions of medicare administrative contractors in carrying out activities under parts A and B do not duplicate activities carried out under the Medicare Integrity Program under section 1893. The previous sentence shall not apply with respect to the activity described in section 1893(b)(5) (relating to prior authorization of certain items of durable medical equipment under section 1834(a)(15)).

"(B) CONSTRUCTION.—An entity shall not be treated as a medicare administrative contractor merely by reason of having entered into a contract with the Secretary under section 1893.

"(6) APPLICATION OF FEDERAL ACQUISITION REGULATION.—Except to the extent inconsistent with a specific requirement of this title, the Federal Acquisition Regulation applies to contracts under this title.

"(b) CONTRACTING REQUIREMENTS.—

"(1) USE OF COMPETITIVE PROCEDURES.—

"(A) IN GENERAL.—Except as provided in laws with general applicability to Federal acquisition and procurement or in subparagraph (B), the Secretary shall use competitive procedures when entering into contracts with medicare administrative contractors under this section, taking into account performance quality as well as price and other factors.

"(B) RENEWAL OF CONTRACTS.—The Secretary may renew a contract with a medicare administrative contractor under this section from term to term without regard to section 5 of title 41, United States Code, or any other provision of law requiring competition, if the medicare administrative contractor has met or exceeded the performance requirements applicable with respect to the contract and contractor, except that the Secretary shall provide for the application of competitive procedures under such a contract not less frequently than once every five years.

"(C) TRANSFER OF FUNCTIONS.—The Secretary may transfer functions among medicare administrative contractors consistent with the provisions of this paragraph. The Secretary shall ensure that performance quality is considered in such transfers. The Secretary shall provide public notice (whether in the Federal Register or otherwise) of any such transfer (including a description of the functions so transferred, a description of the providers of services and suppliers affected by such transfer, and contact information for the contractors involved).

"(D) INCENTIVES FOR QUALITY.—The Secretary shall provide incentives for medicare administrative contractors to provide quality service and to promote efficiency.

"(2) COMPLIANCE WITH REQUIREMENTS.—No contract under this section shall be entered into with any medicare administrative contractor unless the Secretary finds that such medicare administrative contractor will perform its obligations under the contract efficiently and effectively and will meet such requirements as to financial responsibility, legal authority, quality of services provided, and other matters as the Secretary finds pertinent.

"(3) PERFORMANCE REQUIREMENTS.—

"(A) DEVELOPMENT OF SPECIFIC PERFORMANCE REQUIREMENTS.—In developing contract performance requirements, the Secretary shall develop performance requirements applicable to functions described in subsection (a)(4).

"(B) CONSULTATION.— In developing such requirements, the Secretary may consult with providers of services and suppliers, organizations representing individuals entitled to benefits under part A or enrolled under part B, or both, and organizations and agencies performing functions necessary to carry out the purposes of this section with respect to such performance requirements.

"(C) INCLUSION IN CONTRACTS.—All contractor performance requirements shall be set forth in the contract between the Secretary and the appropriate medicare administrative contractor. Such performance requirements—

"(i) shall reflect the performance requirements developed under subparagraph (A), but may include additional performance requirements;

"(ii) shall be used for evaluating contractor performance under the contract; and

"(iii) shall be consistent with the written statement of work provided under the contract.

"(4) INFORMATION REQUIREMENTS.—The Secretary shall not enter into a contract with a medicare administrative contractor under this section unless the contractor agrees—

"(A) to furnish to the Secretary such timely information and reports as the Secretary may find necessary in performing his functions under this title; and

"(B) to maintain such records and afford such access thereto as the Secretary finds necessary to assure the correctness and verification of the information and reports under subparagraph (A) and otherwise to carry out the purposes of this title.

"(5) SURETY BOND.—A contract with a medicare administrative contractor under this section may require the medicare administrative contractor, and any of its officers or employees certifying payments or disbursing funds pursuant to the contract, or otherwise participating in carrying out the contract, to give sur-

ety bond to the United States in such amount as the Secretary may deem appropriate.

"(c) TERMS AND CONDITIONS.—

"(1) IN GENERAL.—A contract with any medicare administrative contractor under this section may contain such terms and conditions as the Secretary finds necessary or appropriate and may provide for advances of funds to the medicare administrative contractor for the making of payments by it under subsection (a)(4)(B).

"(2) PROHIBITION ON MANDATES FOR CERTAIN DATA COLLECTION.—The Secretary may not require, as a condition of entering into, or renewing, a contract under this section, that the medicare administrative contractor match data obtained other than in its activities under this title with data used in the administration of this title for purposes of identifying situations in which the provisions of section 1862(b) may apply.

"(d) LIMITATION ON LIABILITY OF MEDICARE ADMINISTRATIVE CONTRACTORS AND CERTAIN OFFICERS.—

"(1) CERTIFYING OFFICER.—No individual designated pursuant to a contract under this section as a certifying officer shall, in the absence of the reckless disregard of the individual's obligations or the intent by that individual to defraud the United States, be liable with respect to any payments certified by the individual under this section.

"(2) DISBURSING OFFICER.—No disbursing officer shall, in the absence of the reckless disregard of the officer's obligations or the intent by that officer to defraud the United States, be liable with respect to any payment by such officer under this section if it was based upon an authorization (which meets the applicable requirements for such internal controls established by the Comptroller General) of a certifying officer designated as provided in paragraph (1) of this subsection.

"(3) LIABILITY OF MEDICARE ADMINISTRATIVE CONTRACTOR.—

"(A) IN GENERAL.—No medicare administrative contractor shall be liable to the United States for a payment by a certifying or disbursing officer unless, in connection with such payment, the medicare administrative contractor acted with reckless disregard of its obligations under its medicare administrative contract or with intent to defraud the United States.

"(B) RELATIONSHIP TO FALSE CLAIMS ACT.—Nothing in this subsection shall be construed to limit liability for conduct that would constitute a violation of sections 3729 through 3731 of title 31, United States Code (commonly known as the 'False Claims Act').

"(4) INDEMNIFICATION BY SECRETARY.—

"(A) IN GENERAL.—Subject to subparagraphs (B) and (D), in the case of a medicare administrative contractor (or a person who is a director, officer, or employee of such a contractor or who is engaged by the contractor to participate directly in the claims administration process) who is made a party to any judicial or administrative proceeding arising from or relating directly to the claims administration process under this title, the Secretary may, to the extent the Secretary determines to be appropriate and as specified in the contract with the contractor, indemnify the contractor and such persons.

"(B) CONDITIONS.—The Secretary may not provide indemnification under subparagraph (A) insofar as the liability for such costs arises directly from conduct that is determined by the judicial proceeding or by the Secretary to be criminal in nature, fraudulent, or grossly negligent. If indemnification is provided by the Secretary with respect to a contractor before a determination that such costs arose directly from such conduct, the contractor shall reimburse the Secretary for costs of indemnification.

"(C) SCOPE OF INDEMNIFICATION.—Indemnification by the Secretary under subparagraph (A) may include payment of judgments, settlements (subject to subparagraph (D)), awards, and costs (including reasonable legal expenses).

"(D) WRITTEN APPROVAL FOR SETTLEMENTS.—A contractor or other person described in subparagraph (A) may not propose to negotiate a settlement or compromise of a proceeding described in such subparagraph without the prior written approval of the Secretary to negotiate such settlement or compromise. Any indemnification under subparagraph (A) with respect to amounts paid under a settlement or compromise of a proceeding described in such subparagraph are conditioned upon prior written approval by the Secretary of the final settlement or compromise.

"(E) CONSTRUCTION.—Nothing in this paragraph shall be construed—

"(i) to change any common law immunity that may be available to a medicare administrative contractor or person described in subparagraph (A); or

"(ii) to permit the payment of costs not otherwise allowable, reasonable, or allocable under the Federal Acquisition Regulations.".

(2) CONSIDERATION OF INCORPORATION OF CURRENT LAW STANDARDS.—In developing contract performance requirements under section 1874A(b) of the Social Security Act, as inserted by paragraph (1), the Secretary shall consider inclusion of the performance standards described in sections 1816(f)(2) of such Act (relating to timely processing of reconsiderations and applications for exemptions) and section 1842(b)(2)(B) of such Act (relating to timely review of determinations and fair hearing requests), as such sections were in effect before the date of the enactment of this Act.

(b) CONFORMING AMENDMENTS TO SECTION 1816 (RELATING TO FISCAL INTERMEDIARIES).—Section 1816 (42 U.S.C. 1395h) is amended as follows:

(1) The heading is amended to read as follows:

"PROVISIONS RELATING TO THE ADMINISTRATION OF PART A".

(2) Subsection (a) is amended to read as follows:

"(a) The administration of this part shall be conducted through contracts with medicare administrative contractors under section 1874A.".

(3) Subsection (b) is repealed.

(4) Subsection (c) is amended—

(A) by striking paragraph (1); and

(B) in each of paragraphs (2)(A) and (3)(A), by striking "agreement under this section" and inserting "contract under section 1874A that provides for making payments under this part".

(5) Subsections (d) through (i) are repealed.

(6) Subsections (j) and (k) are each amended—

(A) by striking "An agreement with an agency or organization under this section" and inserting "A contract with a medicare administrative contractor under section 1874A with respect to the administration of this part"; and

(B) by striking "such agency or organization" and inserting "such medicare administrative contractor" each place it appears.

(7) Subsection (l) is repealed.

(c) CONFORMING AMENDMENTS TO SECTION 1842 (RELATING TO CARRIERS).—Section 1842 (42 U.S.C. 1395u) is amended as follows:

(1) The heading is amended to read as follows:

"PROVISIONS RELATING TO THE ADMINISTRATION OF PART B".

(2) Subsection (a) is amended to read as follows:

"(a) The administration of this part shall be conducted through contracts with medicare administrative contractors under section 1874A.".

(3) Subsection (b) is amended—

(A) by striking paragraph (1);

(B) in paragraph (2)—

(i) by striking subparagraphs (A) and (B);

(ii) in subparagraph (C), by striking "carriers" and inserting "medicare administrative contractors"; and

(iii) by striking subparagraphs (D) and (E);

(C) in paragraph (3)—

(i) in the matter before subparagraph (A), by striking "Each such contract shall provide that the carrier" and inserting "The Secretary";

(ii) by striking "will" the first place it appears in each of subparagraphs (A), (B), (F), (G), (H), and (L) and inserting "shall";

(iii) in subparagraph (B), in the matter before clause (i), by striking "to the policyholders and subscribers of the carrier" and inserting "to the policyholders and subscribers of the medicare administrative contractor";

(iv) by striking subparagraphs (C), (D), and (E);

(v) in subparagraph (H)—

(I) by striking "if it makes determinations or payments with respect to physicians' services," in the matter preceding clause (i); and

(II) by striking "carrier" and inserting "medicare administrative contractor" in clause (i);

(vi) by striking subparagraph (I);

(vii) in subparagraph (L), by striking the semicolon and inserting a period;

(viii) in the first sentence, after subparagraph (L), by striking "and shall contain" and all that follows through the period; and

(ix) in the seventh sentence, by inserting "medicare administrative contractor," after "carrier,"; and

(D) by striking paragraph (5);

(E) in paragraph (6)(D)(iv), by striking "carrier" and inserting "medicare administrative contractor"; and

(F) in paragraph (7), by striking "the carrier" and inserting "the Secretary" each place it appears.

(4) Subsection (c) is amended—

(A) by striking paragraph (1);

(B) in paragraph (2)(A), by striking "contract under this section which provides for the disbursement of funds, as described in subsection (a)(1)(B)," and inserting "contract under section 1874A that provides for making payments under this part";

(C) in paragraph (3)(A), by striking "subsection (a)(1)(B)" and inserting "section 1874A(a)(3)(B)";

(D) in paragraph (4), in the matter preceding subparagraph (A), by striking "carrier" and inserting "medicare administrative contractor"; and

(E) by striking paragraphs (5) and (6).

(5) Subsections (d), (e), and (f) are repealed.

(6) Subsection (g) is amended by striking "carrier or carriers" and inserting "medicare administrative contractor or contractors".

(7) Subsection (h) is amended—

(A) in paragraph (2)—

(i) by striking "Each carrier having an agreement with the Secretary under subsection (a)" and inserting "The Secretary"; and

(ii) by striking "Each such carrier" and inserting "The Secretary";

(B) in paragraph (3)(A)—

(i) by striking "a carrier having an agreement with the Secretary under subsection (a)" and inserting "medicare administrative contractor having a contract under section 1874A that provides for making payments under this part"; and

(ii) by striking "such carrier" and inserting "such contractor";

(C) in paragraph (3)(B)—

(i) by striking "a carrier" and inserting "a medicare administrative contractor" each place it appears; and

(ii) by striking "the carrier" and inserting "the contractor" each place it appears; and

(D) in paragraphs (5)(A) and (5)(B)(iii), by striking "carriers" and inserting "medicare administrative contractors" each place it appears.

(8) Subsection (l) is amended—

(A) in paragraph (1)(A)(iii), by striking "carrier" and inserting "medicare administrative contractor"; and

(B) in paragraph (2), by striking "carrier" and inserting "medicare administrative contractor".

(9) Subsection (p)(3)(A) is amended by striking "carrier" and inserting "medicare administrative contractor".

(10) Subsection (q)(1)(A) is amended by striking "carrier".

(d) EFFECTIVE DATE; TRANSITION RULE.—

(1) EFFECTIVE DATE.—

(A) IN GENERAL.—Except as otherwise provided in this subsection, the amendments made by this section shall take effect on October 1, 2005, and the Secretary is authorized to take such steps before such date as may be necessary to implement such amendments on a timely basis.

(B) CONSTRUCTION FOR CURRENT CONTRACTS.—Such amendments shall not apply to contracts in effect before the date specified under subparagraph (A) that continue to retain the terms and conditions in effect on such date (except as otherwise provided under this Act, other than under this section) until such date as the contract is let out for competitive bidding under such amendments.

(C) DEADLINE FOR COMPETITIVE BIDDING.—The Secretary shall provide for the letting by competitive bidding of all contracts for functions of medicare administrative contractors for annual contract periods that begin on or after October 1, 2010.

(D) WAIVER OF PROVIDER NOMINATION PROVISIONS DURING TRANSITION.—During the period beginning on the date of the enactment of this Act and

before the date specified under subparagraph (A), the Secretary may enter into new agreements under section 1816 of the Social Security Act (42 U.S.C. 1395h) without regard to any of the provider nomination provisions of such section.

(2) GENERAL TRANSITION RULES.—The Secretary shall take such steps, consistent with paragraph (1)(B) and (1)(C), as are necessary to provide for an appropriate transition from contracts under section 1816 and section 1842 of the Social Security Act (42 U.S.C. 1395h, 1395u) to contracts under section 1874A, as added by subsection (a)(1).

(3) AUTHORIZING CONTINUATION OF MIP FUNCTIONS UNDER CURRENT CONTRACTS AND AGREEMENTS AND UNDER ROLLOVER CONTRACTS.—The provisions contained in the exception in section 1893(d)(2) of the Social Security Act (42 U.S.C. 1395ddd(d)(2)) shall continue to apply notwithstanding the amendments made by this section, and any reference in such provisions to an agreement or contract shall be deemed to include a contract under section 1874A of such Act, as inserted by subsection (a)(1), that continues the activities referred to in such provisions.

(e) REFERENCES.—On and after the effective date provided under subsection (d)(1), any reference to a fiscal intermediary or carrier under title XI or XVIII of the Social Security Act (or any regulation, manual instruction, interpretative rule, statement of policy, or guideline issued to carry out such titles) shall be deemed a reference to an appropriate medicare administrative contractor (as provided under section 1874A of the Social Security Act).

(f) REPORTS ON IMPLEMENTATION.—

(1) PLAN FOR IMPLEMENTATION.—By not later than October 1, 2004, the Secretary shall submit a report to Congress and the Comptroller General of the United States that describes the plan for implementation of the amendments made by this section. The Comptroller General shall conduct an evaluation of such plan and shall submit to Congress, not later than 6 months after the date the report is received, a report on such evaluation and shall include in such report such recommendations as the Comptroller General deems appropriate.

(2) STATUS OF IMPLEMENTATION.—The Secretary shall submit a report to Congress not later than October 1, 2008, that describes the status of implementation of such amendments and that includes a description of the following:

(A) The number of contracts that have been competitively bid as of such date.

(B) The distribution of functions among contracts and contractors.

(C) A timeline for complete transition to full competition.

(D) A detailed description of how the Secretary has modified oversight and management of medicare contractors to adapt to full competition.

SEC. 202. REQUIREMENTS FOR INFORMATION SECURITY FOR MEDICARE ADMINISTRATIVE CONTRACTORS.

(a) IN GENERAL.—Section 1874A, as added by section 201(a)(1), is amended by adding at the end the following new subsection:

"(e) REQUIREMENTS FOR INFORMATION SECURITY.—

"(1) DEVELOPMENT OF INFORMATION SECURITY PROGRAM.—A medicare administrative contractor that performs the functions referred to in subparagraphs (A) and (B) of subsection (a)(4) (relating to determining and making payments) shall implement a contractor-wide information security program to provide information security for the operation and assets of the contractor with respect to such functions under this title. An information security program under this paragraph shall meet the requirements for information security programs imposed on Federal agencies under paragraphs (1) through (8) of section 3544(b) of title 44, United States Code (other than requirements under paragraphs (2)(D)(i), (5)(A), and (5)(B) of such section).

"(2) INDEPENDENT AUDITS.—

"(A) PERFORMANCE OF ANNUAL EVALUATIONS.—Each year a medicare administrative contractor that performs the functions referred to in subparagraphs (A) and (B) of subsection (a)(4) (relating to determining and making payments) shall undergo an evaluation of the information security of the contractor with respect to such functions under this title. The evaluation shall—

"(i) be performed by an entity that meets such requirements for independence as the Inspector General of the Department of Health and Human Services may establish; and

"(ii) test the effectiveness of information security policies, procedures, and practices of a representative subset of the contractor's information systems (as defined in section 3502(8) of title 44, United States Code) relating to such functions under this title and an assessment of compli-

ance with the requirements of this subsection and related information security policies, procedures, standards and guidelines, including policies and procedures as may be prescribed by the Director of the Office of Management and Budget and applicable information security standards promulgated under section 11331 of title 40, United States Code.

"(B) DEADLINE FOR INITIAL EVALUATION.—

"(i) NEW CONTRACTORS.—In the case of a medicare administrative contractor covered by this subsection that has not previously performed the functions referred to in subparagraphs (A) and (B) of subsection (a)(4) (relating to determining and making payments) as a fiscal intermediary or carrier under section 1816 or 1842, the first independent evaluation conducted pursuant subparagraph (A) shall be completed prior to commencing such functions.

"(ii) OTHER CONTRACTORS.—In the case of a medicare administrative contractor covered by this subsection that is not described in clause (i), the first independent evaluation conducted pursuant subparagraph (A) shall be completed within 1 year after the date the contractor commences functions referred to in clause (i) under this section.

"(C) REPORTS ON EVALUATIONS.—

"(i) TO THE DEPARTMENT OF HEALTH AND HUMAN SERVICES.—The results of independent evaluations under subparagraph (A) shall be submitted promptly to the Inspector General of the Department of Health and Human Services and to the Secretary.

"(ii) TO CONGRESS.—The Inspector General of Department of Health and Human Services shall submit to Congress annual reports on the results of such evaluations, including assessments of the scope and sufficiency of such evaluations.

"(iii) AGENCY REPORTING.—The Secretary shall address the results of such evaluations in reports required under section 3544(c) of title 44, United States Code.".

(b) APPLICATION OF REQUIREMENTS TO FISCAL INTERMEDIARIES AND CARRIERS.—

(1) IN GENERAL.—The provisions of section 1874A(e)(2) of the Social Security Act (other than subparagraph (B)), as added by subsection (a), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions.

(2) DEADLINE FOR INITIAL EVALUATION.—In the case of such a fiscal intermediary or carrier with an agreement or contract under such respective section in effect as of the date of the enactment of this Act, the first evaluation under section 1874A(e)(2)(A) of the Social Security Act (as added by subsection (a)), pursuant to paragraph (1), shall be completed (and a report on the evaluation submitted to the Secretary) by not later than 1 year after such date.

TITLE III—EDUCATION AND OUTREACH

SEC. 301. PROVIDER EDUCATION AND TECHNICAL ASSISTANCE.

(a) COORDINATION OF EDUCATION FUNDING.—

(1) IN GENERAL.—The Social Security Act is amended by inserting after section 1888 the following new section:

"PROVIDER EDUCATION AND TECHNICAL ASSISTANCE

"SEC. 1889. (a) COORDINATION OF EDUCATION FUNDING.—The Secretary shall coordinate the educational activities provided through medicare contractors (as defined in subsection (g), including under section 1893) in order to maximize the effectiveness of Federal education efforts for providers of services and suppliers.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on the date of the enactment of this Act.

(3) REPORT.—Not later than October 1, 2004, the Secretary shall submit to Congress a report that includes a description and evaluation of the steps taken to coordinate the funding of provider education under section 1889(a) of the Social Security Act, as added by paragraph (1).

(b) INCENTIVES TO IMPROVE CONTRACTOR PERFORMANCE.—

(1) IN GENERAL.—Section 1874A, as added by section 201(a)(1) and as amended by section 202(a), is amended by adding at the end the following new subsection:

"(f) INCENTIVES TO IMPROVE CONTRACTOR PERFORMANCE IN PROVIDER EDUCATION AND OUTREACH.—The Secretary shall use specific claims payment error rates or similar methodology of medicare administrative contractors in the processing or reviewing of medicare claims in order to give such contractors an incentive to implement effective education and outreach programs for providers of services and suppliers.".

(2) APPLICATION TO FISCAL INTERMEDIARIES AND CARRIERS.—The provisions of section 1874A(f) of the Social Security Act, as added by paragraph (1), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions.

(3) GAO REPORT ON ADEQUACY OF METHODOLOGY.—Not later than October 1, 2004, the Comptroller General of the United States shall submit to Congress and to the Secretary a report on the adequacy of the methodology under section 1874A(f) of the Social Security Act, as added by paragraph (1), and shall include in the report such recommendations as the Comptroller General determines appropriate with respect to the methodology.

(4) REPORT ON USE OF METHODOLOGY IN ASSESSING CONTRACTOR PERFORMANCE.—Not later than October 1, 2004, the Secretary shall submit to Congress a report that describes how the Secretary intends to use such methodology in assessing medicare contractor performance in implementing effective education and outreach programs, including whether to use such methodology as a basis for performance bonuses. The report shall include an analysis of the sources of identified errors and potential changes in systems of contractors and rules of the Secretary that could reduce claims error rates.

(c) PROVISION OF ACCESS TO AND PROMPT RESPONSES FROM MEDICARE ADMINISTRATIVE CONTRACTORS.—

(1) IN GENERAL.—Section 1874A, as added by section 201(a)(1) and as amended by section 202(a) and subsection (b), is further amended by adding at the end the following new subsection:

"(g) COMMUNICATIONS WITH BENEFICIARIES, PROVIDERS OF SERVICES AND SUPPLIERS.—

"(1) COMMUNICATION STRATEGY.—The Secretary shall develop a strategy for communications with individuals entitled to benefits under part A or enrolled under part B, or both, and with providers of services and suppliers under this title.

"(2) RESPONSE TO WRITTEN INQUIRIES.—Each medicare administrative contractor shall, for those providers of services and suppliers which submit claims to the contractor for claims processing and for those individuals entitled to benefits under part A or enrolled under part B, or both, with respect to whom claims are submitted for claims processing, provide general written responses (which may be through electronic transmission) in a clear, concise, and accurate manner to inquiries of providers of services, suppliers and individuals entitled to benefits under part A or enrolled under part B, or both, concerning the programs under this title within 45 business days of the date of receipt of such inquiries.

"(3) RESPONSE TO TOLL-FREE LINES.—The Secretary shall ensure that each medicare administrative contractor shall provide, for those providers of services and suppliers which submit claims to the contractor for claims processing and for those individuals entitled to benefits under part A or enrolled under part B, or both, with respect to whom claims are submitted for claims processing, a toll-free telephone number at which such individuals, providers of services and suppliers may obtain information regarding billing, coding, claims, coverage, and other appropriate information under this title.

"(4) MONITORING OF CONTRACTOR RESPONSES.—

"(A) IN GENERAL.—Each medicare administrative contractor shall, consistent with standards developed by the Secretary under subparagraph (B)—

"(i) maintain a system for identifying who provides the information referred to in paragraphs (2) and (3); and

"(ii) monitor the accuracy, consistency, and timeliness of the information so provided.

"(B) DEVELOPMENT OF STANDARDS.—

"(i) IN GENERAL.—The Secretary shall establish and make public standards to monitor the accuracy, consistency, and timeliness of the information provided in response to written and telephone inquiries under this subsection. Such standards shall be consistent with the performance requirements established under subsection (b)(3).

"(ii) EVALUATION.—In conducting evaluations of individual medicare administrative contractors, the Secretary shall take into account the results of the monitoring conducted under subparagraph (A) taking into account as performance requirements the standards established under clause (i). The Secretary shall, in consultation with organizations representing providers of services, suppliers, and individuals entitled to benefits under part A or enrolled under part B, or both, establish standards relating to the accuracy, consistency, and timeliness of the information so provided.

"(C) DIRECT MONITORING.—Nothing in this paragraph shall be construed as preventing the Secretary from directly monitoring the accuracy, consistency, and timeliness of the information so provided.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect October 1, 2004.

(3) APPLICATION TO FISCAL INTERMEDIARIES AND CARRIERS.—The provisions of section 1874A(g) of the Social Security Act, as added by paragraph (1), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions.

(d) IMPROVED PROVIDER EDUCATION AND TRAINING.—

(1) IN GENERAL.—Section 1889, as added by subsection (a), is amended by adding at the end the following new subsections:

"(b) ENHANCED EDUCATION AND TRAINING.—

"(1) ADDITIONAL RESOURCES.—There are authorized to be appropriated to the Secretary (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) $25,000,000 for each of fiscal years 2005 and 2006 and such sums as may be necessary for succeeding fiscal years.

"(2) USE.—The funds made available under paragraph (1) shall be used to increase the conduct by medicare contractors of education and training of providers of services and suppliers regarding billing, coding, and other appropriate items and may also be used to improve the accuracy, consistency, and timeliness of contractor responses.

"(c) TAILORING EDUCATION AND TRAINING ACTIVITIES FOR SMALL PROVIDERS OR SUPPLIERS.—

"(1) IN GENERAL.—Insofar as a medicare contractor conducts education and training activities, it shall tailor such activities to meet the special needs of small providers of services or suppliers (as defined in paragraph (2)).

"(2) SMALL PROVIDER OF SERVICES OR SUPPLIER.—In this subsection, the term 'small provider of services or supplier' means—

"(A) a provider of services with fewer than 25 full-time-equivalent employees; or

"(B) a supplier with fewer than 10 full-time-equivalent employees.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on October 1, 2004.

(e) REQUIREMENT TO MAINTAIN INTERNET SITES.—

(1) IN GENERAL.—Section 1889, as added by subsection (a) and as amended by subsection (d), is further amended by adding at the end the following new subsection:

"(d) INTERNET SITES; FAQS.—The Secretary, and each medicare contractor insofar as it provides services (including claims processing) for providers of services or suppliers, shall maintain an Internet site which—

"(1) provides answers in an easily accessible format to frequently asked questions, and

"(2) includes other published materials of the contractor,

that relate to providers of services and suppliers under the programs under this title (and title XI insofar as it relates to such programs).".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on October 1, 2004.

(f) ADDITIONAL PROVIDER EDUCATION PROVISIONS.—

(1) IN GENERAL.—Section 1889, as added by subsection (a) and as amended by subsections (d) and (e), is further amended by adding at the end the following new subsections:

"(e) ENCOURAGEMENT OF PARTICIPATION IN EDUCATION PROGRAM ACTIVITIES.—A medicare contractor may not use a record of attendance at (or failure to attend) educational activities or other information gathered during an educational program conducted under this section or otherwise by the Secretary to select or track providers

of services or suppliers for the purpose of conducting any type of audit or prepayment review.

"(f) CONSTRUCTION.—Nothing in this section or section 1893(g) shall be construed as providing for disclosure by a medicare contractor of information that would compromise pending law enforcement activities or reveal findings of law enforcement-related audits.

"(g) DEFINITIONS.—For purposes of this section, the term 'medicare contractor' includes the following:

"(1) A medicare administrative contractor with a contract under section 1874A, including a fiscal intermediary with a contract under section 1816 and a carrier with a contract under section 1842.

"(2) An eligible entity with a contract under section 1893.

Such term does not include, with respect to activities of a specific provider of services or supplier an entity that has no authority under this title or title IX with respect to such activities and such provider of services or supplier.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on the date of the enactment of this Act.

SEC. 302. SMALL PROVIDER TECHNICAL ASSISTANCE DEMONSTRATION PROGRAM.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—The Secretary shall establish a demonstration program (in this section referred to as the "demonstration program") under which technical assistance described in paragraph (2) is made available, upon request and on a voluntary basis, to small providers of services or suppliers in order to improve compliance with the applicable requirements of the programs under medicare program under title XVIII of the Social Security Act (including provisions of title XI of such Act insofar as they relate to such title and are not administered by the Office of the Inspector General of the Department of Health and Human Services).

(2) FORMS OF TECHNICAL ASSISTANCE.—The technical assistance described in this paragraph is—

(A) evaluation and recommendations regarding billing and related systems; and

(B) information and assistance regarding policies and procedures under the medicare program, including coding and reimbursement.

(3) SMALL PROVIDERS OF SERVICES OR SUPPLIERS.—In this section, the term "small providers of services or suppliers" means—

(A) a provider of services with fewer than 25 full-time-equivalent employees; or

(B) a supplier with fewer than 10 full-time-equivalent employees.

(b) QUALIFICATION OF CONTRACTORS.—In conducting the demonstration program, the Secretary shall enter into contracts with qualified organizations (such as peer review organizations or entities described in section 1889(g)(2) of the Social Security Act, as inserted by section 5(f)(1)) with appropriate expertise with billing systems of the full range of providers of services and suppliers to provide the technical assistance. In awarding such contracts, the Secretary shall consider any prior investigations of the entity's work by the Inspector General of Department of Health and Human Services or the Comptroller General of the United States.

(c) DESCRIPTION OF TECHNICAL ASSISTANCE.—The technical assistance provided under the demonstration program shall include a direct and in-person examination of billing systems and internal controls of small providers of services or suppliers to determine program compliance and to suggest more efficient or effective means of achieving such compliance.

(d) AVOIDANCE OF RECOVERY ACTIONS FOR PROBLEMS IDENTIFIED AS CORRECTED.—The Secretary shall provide that, absent evidence of fraud and notwithstanding any other provision of law, any errors found in a compliance review for a small provider of services or supplier that participates in the demonstration program shall not be subject to recovery action if the technical assistance personnel under the program determine that—

(1) the problem that is the subject of the compliance review has been corrected to their satisfaction within 30 days of the date of the visit by such personnel to the small provider of services or supplier; and

(2) such problem remains corrected for such period as is appropriate.

The previous sentence applies only to claims filed as part of the demonstration program and lasts only for the duration of such program and only as long as the small provider of services or supplier is a participant in such program.

(e) GAO EVALUATION.—Not later than 2 years after the date of the date the demonstration program is first implemented, the Comptroller General, in consultation with the Inspector General of the Department of Health and Human Services, shall

conduct an evaluation of the demonstration program. The evaluation shall include a determination of whether claims error rates are reduced for small providers of services or suppliers who participated in the program and the extent of improper payments made as a result of the demonstration program. The Comptroller General shall submit a report to the Secretary and the Congress on such evaluation and shall include in such report recommendations regarding the continuation or extension of the demonstration program.

(f) FINANCIAL PARTICIPATION BY PROVIDERS.—The provision of technical assistance to a small provider of services or supplier under the demonstration program is conditioned upon the small provider of services or supplier paying an amount estimated (and disclosed in advance of a provider's or supplier's participation in the program) to be equal to 25 percent of the cost of the technical assistance.

(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) to carry out the demonstration program—

(1) for fiscal year 2005, $1,000,000, and

(2) for fiscal year 2006, $6,000,000.

SEC. 303. MEDICARE PROVIDER OMBUDSMAN; MEDICARE BENEFICIARY OMBUDSMAN.

(a) MEDICARE PROVIDER OMBUDSMAN.—Section 1868 (42 U.S.C. 1395ee) is amended—

(1) by adding at the end of the heading the following: "; MEDICARE PROVIDER OMBUDSMAN";

(2) by inserting "PRACTICING PHYSICIANS ADVISORY COUNCIL.—(1)" after "(a)";

(3) in paragraph (1), as so redesignated under paragraph (2), by striking "in this section" and inserting "in this subsection";

(4) by redesignating subsections (b) and (c) as paragraphs (2) and (3), respectively; and

(5) by adding at the end the following new subsection:

"(b) MEDICARE PROVIDER OMBUDSMAN.—The Secretary shall appoint within the Department of Health and Human Services a Medicare Provider Ombudsman. The Ombudsman shall—

"(1) provide assistance, on a confidential basis, to providers of services and suppliers with respect to complaints, grievances, and requests for information concerning the programs under this title (including provisions of title XI insofar as they relate to this title and are not administered by the Office of the Inspector General of the Department of Health and Human Services) and in the resolution of unclear or conflicting guidance given by the Secretary and medicare contractors to such providers of services and suppliers regarding such programs and provisions and requirements under this title and such provisions; and

"(2) submit recommendations to the Secretary for improvement in the administration of this title and such provisions, including—

"(A) recommendations to respond to recurring patterns of confusion in this title and such provisions (including recommendations regarding suspending imposition of sanctions where there is widespread confusion in program administration), and

"(B) recommendations to provide for an appropriate and consistent response (including not providing for audits) in cases of self-identified overpayments by providers of services and suppliers.

The Ombudsman shall not serve as an advocate for any increases in payments or new coverage of services, but may identify issues and problems in payment or coverage policies.".

(b) MEDICARE BENEFICIARY OMBUDSMAN.—Title XVIII is amended by inserting after section 1806 the following new section:

"MEDICARE BENEFICIARY OMBUDSMAN

"SEC. 1807. (a) IN GENERAL.—The Secretary shall appoint within the Department of Health and Human Services a Medicare Beneficiary Ombudsman who shall have expertise and experience in the fields of health care and education of (and assistance to) individuals entitled to benefits under this title.

"(b) DUTIES.—The Medicare Beneficiary Ombudsman shall—

"(1) receive complaints, grievances, and requests for information submitted by individuals entitled to benefits under part A or enrolled under part B, or both, with respect to any aspect of the medicare program;

"(2) provide assistance with respect to complaints, grievances, and requests referred to in paragraph (1), including—

"(A) assistance in collecting relevant information for such individuals, to seek an appeal of a decision or determination made by a fiscal intermediary, carrier, Medicare+Choice organization, or the Secretary; and

"(B) assistance to such individuals with any problems arising from disenrollment from a Medicare+Choice plan under part C; and

"(3) submit annual reports to Congress and the Secretary that describe the activities of the Office and that include such recommendations for improvement in the administration of this title as the Ombudsman determines appropriate.

The Ombudsman shall not serve as an advocate for any increases in payments or new coverage of services, but may identify issues and problems in payment or coverage policies.

"(c) WORKING WITH HEALTH INSURANCE COUNSELING PROGRAMS.—To the extent possible, the Ombudsman shall work with health insurance counseling programs (receiving funding under section 4360 of Omnibus Budget Reconciliation Act of 1990) to facilitate the provision of information to individuals entitled to benefits under part A or enrolled under part B, or both regarding Medicare+Choice plans and changes to those plans. Nothing in this subsection shall preclude further collaboration between the Ombudsman and such programs.".

(c) DEADLINE FOR APPOINTMENT.—The Secretary shall appoint the Medicare Provider Ombudsman and the Medicare Beneficiary Ombudsman, under the amendments made by subsections (a) and (b), respectively, by not later than 1 year after the date of the enactment of this Act.

(d) FUNDING.—There are authorized to be appropriated to the Secretary (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) to carry out the provisions of subsection (b) of section 1868 of the Social Security Act (relating to the Medicare Provider Ombudsman), as added by subsection (a)(5) and section 1807 of such Act (relating to the Medicare Beneficiary Ombudsman), as added by subsection (b), such sums as are necessary for fiscal year 2004 and each succeeding fiscal year.

(e) USE OF CENTRAL, TOLL-FREE NUMBER (1–800–MEDICARE).—

(1) PHONE TRIAGE SYSTEM; LISTING IN MEDICARE HANDBOOK INSTEAD OF OTHER TOLL-FREE NUMBERS.—Section 1804(b) (42 U.S.C. 1395b–2(b)) is amended by adding at the end the following: "The Secretary shall provide, through the toll-free number 1–800–MEDICARE, for a means by which individuals seeking information about, or assistance with, such programs who phone such toll-free number are transferred (without charge) to appropriate entities for the provision of such information or assistance. Such toll-free number shall be the toll-free number listed for general information and assistance in the annual notice under subsection (a) instead of the listing of numbers of individual contractors.".

(2) MONITORING ACCURACY.—

(A) STUDY.—The Comptroller General of the United States shall conduct a study to monitor the accuracy and consistency of information provided to individuals entitled to benefits under part A or enrolled under part B, or both, through the toll-free number 1–800–MEDICARE, including an assessment of whether the information provided is sufficient to answer questions of such individuals. In conducting the study, the Comptroller General shall examine the education and training of the individuals providing information through such number.

(B) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report on the study conducted under subparagraph (A).

SEC. 304. BENEFICIARY OUTREACH DEMONSTRATION PROGRAM.

(a) IN GENERAL.—The Secretary shall establish a demonstration program (in this section referred to as the "demonstration program") under which medicare specialists employed by the Department of Health and Human Services provide advice and assistance to individuals entitled to benefits under part A of title XVIII of the Social Security Act, or enrolled under part B of such title, or both, regarding the medicare program at the location of existing local offices of the Social Security Administration.

(b) LOCATIONS.—

(1) IN GENERAL.—The demonstration program shall be conducted in at least 6 offices or areas. Subject to paragraph (2), in selecting such offices and areas, the Secretary shall provide preference for offices with a high volume of visits by individuals referred to in subsection (a).

(2) ASSISTANCE FOR RURAL BENEFICIARIES.—The Secretary shall provide for the selection of at least 2 rural areas to participate in the demonstration program. In conducting the demonstration program in such rural areas, the Sec-

retary shall provide for medicare specialists to travel among local offices in a rural area on a scheduled basis.

(c) DURATION.—The demonstration program shall be conducted over a 3-year period.

(d) EVALUATION AND REPORT.—

(1) EVALUATION.—The Secretary shall provide for an evaluation of the demonstration program. Such evaluation shall include an analysis of—

(A) utilization of, and satisfaction of those individuals referred to in subsection (a) with, the assistance provided under the program; and

(B) the cost-effectiveness of providing beneficiary assistance through outstationing medicare specialists at local offices of the Social Security Administration.

(2) REPORT.—The Secretary shall submit to Congress a report on such evaluation and shall include in such report recommendations regarding the feasibility of permanently out-stationing medicare specialists at local offices of the Social Security Administration.

SEC. 305. INCLUSION OF ADDITIONAL INFORMATION IN NOTICES TO BENEFICIARIES ABOUT SKILLED NURSING FACILITY BENEFITS.

(a) IN GENERAL.—The Secretary shall provide that in medicare beneficiary notices provided (under section 1806(a) of the Social Security Act, 42 U.S.C. 1395b–7(a)) with respect to the provision of post-hospital extended care services under part A of title XVIII of the Social Security Act, there shall be included information on the number of days of coverage of such services remaining under such part for the medicare beneficiary and spell of illness involved.

(b) EFFECTIVE DATE.—Subsection (a) shall apply to notices provided during calendar quarters beginning more than 6 months after the date of the enactment of this Act.

SEC. 306. INFORMATION ON MEDICARE-CERTIFIED SKILLED NURSING FACILITIES IN HOSPITAL DISCHARGE PLANS.

(a) AVAILABILITY OF DATA.—The Secretary shall publicly provide information that enables hospital discharge planners, medicare beneficiaries, and the public to identify skilled nursing facilities that are participating in the medicare program.

(b) INCLUSION OF INFORMATION IN CERTAIN HOSPITAL DISCHARGE PLANS.—

(1) IN GENERAL.—Section 1861(ee)(2)(D) (42 U.S.C. 1395x(ee)(2)(D)) is amended—

(A) by striking "hospice services" and inserting "hospice care and post-hospital extended care services"; and

(B) by inserting before the period at the end the following: "and, in the case of individuals who are likely to need post-hospital extended care services, the availability of such services through facilities that participate in the program under this title and that serve the area in which the patient resides".

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to discharge plans made on or after such date as the Secretary shall specify, but not later than 6 months after the date the Secretary provides for availability of information under subsection (a).

TITLE IV—APPEALS AND RECOVERY

SEC. 401. TRANSFER OF RESPONSIBILITY FOR MEDICARE APPEALS.

(a) TRANSITION PLAN.—

(1) IN GENERAL.—Not later than October 1, 2004, the Commissioner of Social Security and the Secretary shall develop and transmit to Congress and the Comptroller General of the United States a plan under which the functions of administrative law judges responsible for hearing cases under title XVIII of the Social Security Act (and related provisions in title XI of such Act) are transferred from the responsibility of the Commissioner and the Social Security Administration to the Secretary and the Department of Health and Human Services.

(2) GAO EVALUATION.—The Comptroller General of the United States shall evaluate the plan and, not later than the date that is 6 months after the date on which the plan is received by the Comptroller General, shall submit to Congress a report on such evaluation.

(b) TRANSFER OF ADJUDICATION AUTHORITY.—

(1) IN GENERAL.—Not earlier than July 1, 2005, and not later than October 1, 2005, the Commissioner of Social Security and the Secretary shall implement the transition plan under subsection (a) and transfer the administrative law

judge functions described in such subsection from the Social Security Administration to the Secretary.

(2) ASSURING INDEPENDENCE OF JUDGES.—The Secretary shall assure the independence of administrative law judges performing the administrative law judge functions transferred under paragraph (1) from the Centers for Medicare & Medicaid Services and its contractors. In order to assure such independence, the Secretary shall place such judges in an administrative office that is organizationally and functionally separate from such Centers. Such judges shall report to, and be under the general supervision of, the Secretary (or, to the extent the Secretary delegates such authority, the officer next in rank below the Secretary), but shall not report to, or be subject to supervision by, any other officer of the Department.

(3) GEOGRAPHIC DISTRIBUTION.—The Secretary shall provide for an appropriate geographic distribution of administrative law judges performing the administrative law judge functions transferred under paragraph (1) throughout the United States to ensure timely access to such judges.

(4) HIRING AUTHORITY.—Subject to the amounts provided in advance in appropriations Act, the Secretary shall have authority to hire administrative law judges to hear such cases, giving priority to those judges with prior experience in handling medicare appeals and in a manner consistent with paragraph (3), and to hire support staff for such judges.

(5) FINANCING.—Amounts payable under law to the Commissioner for administrative law judges performing the administrative law judge functions transferred under paragraph (1) from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund shall become payable to the Secretary for the functions so transferred.

(6) SHARED RESOURCES.—The Secretary shall enter into such arrangements with the Commissioner as may be appropriate with respect to transferred functions of administrative law judges to share office space, support staff, and other resources, with appropriate reimbursement from the Trust Funds described in paragraph (5).

(c) INCREASED FINANCIAL SUPPORT.—In addition to any amounts otherwise appropriated, to ensure timely action on appeals before administrative law judges and the Departmental Appeals Board consistent with section 1869 of the Social Security Act (as amended by section 521 of BIPA, 114 Stat. 2763A–534), there are authorized to be appropriated (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) to the Secretary such sums as are necessary for fiscal year 2005 and each subsequent fiscal year to—

(1) increase the number of administrative law judges (and their staffs) under subsection (b)(4);

(2) improve education and training opportunities for administrative law judges (and their staffs); and

(3) increase the staff of the Departmental Appeals Board.

(d) CONFORMING AMENDMENT.—Section 1869(f)(2)(A)(i) (42 U.S.C. 1395ff(f)(2)(A)(i)), as added by section 522(a) of BIPA (114 Stat. 2763A–543), is amended by striking "of the Social Security Administration".

SEC. 402. PROCESS FOR EXPEDITED ACCESS TO REVIEW.

(a) EXPEDITED ACCESS TO JUDICIAL REVIEW.—Section 1869(b) (42 U.S.C. 1395ff(b)) as amended by BIPA, is amended—

(1) in paragraph (1)(A), by inserting ", subject to paragraph (2)," before "to judicial review of the Secretary's final decision";

(2) in paragraph (1)(F)—

(A) by striking clause (ii);

(B) by striking "PROCEEDING" and all that follows through "DETERMINATION" and inserting "DETERMINATIONS AND RECONSIDERATIONS"; and

(C) by redesignating subclauses (I) and (II) as clauses (i) and (ii) and by moving the indentation of such subclauses (and the matter that follows) 2 ems to the left; and

(3) by adding at the end the following new paragraph:

"(2) EXPEDITED ACCESS TO JUDICIAL REVIEW.—

"(A) IN GENERAL.—The Secretary shall establish a process under which a provider of services or supplier that furnishes an item or service or an individual entitled to benefits under part A or enrolled under part B, or both, who has filed an appeal under paragraph (1) may obtain access to judicial review when a review panel (described in subparagraph (D)), on its own motion or at the request of the appellant, determines that no entity in the administrative appeals process has the authority to decide the ques-

tion of law or regulation relevant to the matters in controversy and that there is no material issue of fact in dispute. The appellant may make such request only once with respect to a question of law or regulation in a case of an appeal.

"(B) PROMPT DETERMINATIONS.—If, after or coincident with appropriately filing a request for an administrative hearing, the appellant requests a determination by the appropriate review panel that no review panel has the authority to decide the question of law or regulations relevant to the matters in controversy and that there is no material issue of fact in dispute and if such request is accompanied by the documents and materials as the appropriate review panel shall require for purposes of making such determination, such review panel shall make a determination on the request in writing within 60 days after the date such review panel receives the request and such accompanying documents and materials. Such a determination by such review panel shall be considered a final decision and not subject to review by the Secretary.

"(C) ACCESS TO JUDICIAL REVIEW.—

"(i) IN GENERAL.—If the appropriate review panel—

"(I) determines that there are no material issues of fact in dispute and that the only issue is one of law or regulation that no review panel has the authority to decide; or

"(II) fails to make such determination within the period provided under subparagraph (B);

then the appellant may bring a civil action as described in this subparagraph.

"(ii) DEADLINE FOR FILING.—Such action shall be filed, in the case described in—

"(I) clause (i)(I), within 60 days of date of the determination described in such subparagraph; or

"(II) clause (i)(II), within 60 days of the end of the period provided under subparagraph (B) for the determination.

"(iii) VENUE.—Such action shall be brought in the district court of the United States for the judicial district in which the appellant is located (or, in the case of an action brought jointly by more than one applicant, the judicial district in which the greatest number of applicants are located) or in the district court for the District of Columbia.

"(iv) INTEREST ON AMOUNTS IN CONTROVERSY.—Where a provider of services or supplier seeks judicial review pursuant to this paragraph, the amount in controversy shall be subject to annual interest beginning on the first day of the first month beginning after the 60-day period as determined pursuant to clause (ii) and equal to the rate of interest on obligations issued for purchase by the Federal Hospital Insurance Trust Fund and by the Federal Supplementary Medical Insurance Trust Fund for the month in which the civil action authorized under this paragraph is commenced, to be awarded by the reviewing court in favor of the prevailing party. No interest awarded pursuant to the preceding sentence shall be deemed income or cost for the purposes of determining reimbursement due providers of services or suppliers under this Act.

"(D) REVIEW PANELS.—For purposes of this subsection, a 'review panel' is a panel consisting of 3 members (who shall be administrative law judges, members of the Departmental Appeals Board, or qualified individuals associated with a qualified independent contractor (as defined in subsection (c)(2)) or with another independent entity) designated by the Secretary for purposes of making determinations under this paragraph.".

(b) APPLICATION TO PROVIDER AGREEMENT DETERMINATIONS.—Section 1866(h)(1) (42 U.S.C. 1395cc(h)(1)) is amended—

(1) by inserting "(A)" after "(h)(1)"; and

(2) by adding at the end the following new subparagraph:

"(B) An institution or agency described in subparagraph (A) that has filed for a hearing under subparagraph (A) shall have expedited access to judicial review under this subparagraph in the same manner as providers of services, suppliers, and individuals entitled to benefits under part A or enrolled under part B, or both, may obtain expedited access to judicial review under the process established under section 1869(b)(2). Nothing in this subparagraph shall be construed to affect the application of any remedy imposed under section 1819 during the pendency of an appeal under this subparagraph.".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to appeals filed on or after October 1, 2004.

(d) EXPEDITED REVIEW OF CERTAIN PROVIDER AGREEMENT DETERMINATIONS.—

(1) TERMINATION AND CERTAIN OTHER IMMEDIATE REMEDIES.—The Secretary shall develop and implement a process to expedite proceedings under sections 1866(h) of the Social Security Act (42 U.S.C. 1395cc(h)) in which the remedy of termination of participation, or a remedy described in clause (i) or (iii) of section 1819(h)(2)(B) of such Act (42 U.S.C. 1395i–3(h)(2)(B)) which is applied on an immediate basis, has been imposed. Under such process priority shall be provided in cases of termination.

(2) INCREASED FINANCIAL SUPPORT.—In addition to any amounts otherwise appropriated, to reduce by 50 percent the average time for administrative determinations on appeals under section 1866(h) of the Social Security Act (42 U.S.C. 1395cc(h)), there are authorized to be appropriated (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) to the Secretary such additional sums for fiscal year 2005 and each subsequent fiscal year as may be necessary. The purposes for which such amounts are available include increasing the number of administrative law judges (and their staffs) and the appellate level staff at the Departmental Appeals Board of the Department of Health and Human Services and educating such judges and staffs on long-term care issues.

(e) PROCESS FOR REINSTATEMENT OF APPROVAL OF CERTAIN SNF TRAINING PROGRAMS.—

(1) IN GENERAL.—In the case of a termination of approval of a nurse aide training program described in paragraph (2) of a skilled nursing facility, the Secretary shall develop and implement a process for the reinstatement of approval of such program before the end of the mandatory 2 year disapproval period if the facility and program is certified by the Secretary, in coordination with the applicable State survey and certification agency and after public notice, as being in compliance with applicable requirements and as having remedied any deficiencies in the facility or program that resulted in noncompliance.

(2) TERMINATION OF APPROVAL DESCRIBED.—A termination of approval of a training program described in this paragraph is a mandatory 2-year disapproval provided for under section 1819(f)(2)(B)(iii) of the Social Security Act (42 U.S.C. 1395i–3(f)(2)(B)(iii)) if the only basis for the mandatory disapproval was the assessment of a civil money penalty of not less than $5,000.

SEC. 403. REVISIONS TO MEDICARE APPEALS PROCESS.

(a) REQUIRING FULL AND EARLY PRESENTATION OF EVIDENCE.—

(1) IN GENERAL.—Section 1869(b) (42 U.S.C. 1395ff(b)), as amended by BIPA and as amended by section 402(a), is further amended by adding at the end the following new paragraph:

"(3) REQUIRING FULL AND EARLY PRESENTATION OF EVIDENCE BY PROVIDERS.—A provider of services or supplier may not introduce evidence in any appeal under this section that was not presented at the reconsideration conducted by the qualified independent contractor under subsection (c), unless there is good cause which precluded the introduction of such evidence at or before that reconsideration.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on October 1, 2004.

(b) USE OF PATIENTS' MEDICAL RECORDS.—Section 1869(c)(3)(B)(i) (42 U.S.C. 1395ff(c)(3)(B)(i)), as amended by BIPA, is amended by inserting "(including the medical records of the individual involved)" after "clinical experience".

(c) NOTICE REQUIREMENTS FOR MEDICARE APPEALS.—

(1) INITIAL DETERMINATIONS AND REDETERMINATIONS.—Section 1869(a) (42 U.S.C. 1395ff(a)), as amended by BIPA, is amended by adding at the end the following new paragraphs:

"(4) REQUIREMENTS OF NOTICE OF DETERMINATIONS.—With respect to an initial determination insofar as it results in a denial of a claim for benefits—

"(A) the written notice on the determination shall include—

"(i) the reasons for the determination, including whether a local medical review policy or a local coverage determination was used;

"(ii) the procedures for obtaining additional information concerning the determination, including the information described in subparagraph (B); and

"(iii) notification of the right to seek a redetermination or otherwise appeal the determination and instructions on how to initiate such a redetermination under this section; and

"(B) the person provided such notice may obtain, upon request, the specific provision of the policy, manual, or regulation used in making the determination.

"(5) REQUIREMENTS OF NOTICE OF REDETERMINATIONS.—With respect to a redetermination insofar as it results in a denial of a claim for benefits—

"(A) the written notice on the redetermination shall include—

"(i) the specific reasons for the redetermination;

"(ii) as appropriate, a summary of the clinical or scientific evidence used in making the redetermination;

"(iii) a description of the procedures for obtaining additional information concerning the redetermination; and

"(iv) notification of the right to appeal the redetermination and instructions on how to initiate such an appeal under this section;

"(B) such written notice shall be provided in printed form and written in a manner calculated to be understood by the individual entitled to benefits under part A or enrolled under part B, or both; and

"(C) the person provided such notice may obtain, upon request, information on the specific provision of the policy, manual, or regulation used in making the redetermination.".

(2) RECONSIDERATIONS.—Section 1869(c)(3)(E) (42 U.S.C. 1395ff(c)(3)(E)), as amended by BIPA, is amended—

(A) by inserting "be written in a manner calculated to be understood by the individual entitled to benefits under part A or enrolled under part B, or both, and shall include (to the extent appropriate)" after "in writing, "; and

(B) by inserting "and a notification of the right to appeal such determination and instructions on how to initiate such appeal under this section" after "such decision,".

(3) APPEALS.—Section 1869(d) (42 U.S.C. 1395ff(d)), as amended by BIPA, is amended—

(A) in the heading, by inserting "; NOTICE" after "SECRETARY"; and

(B) by adding at the end the following new paragraph:

"(4) NOTICE.—Notice of the decision of an administrative law judge shall be in writing in a manner calculated to be understood by the individual entitled to benefits under part A or enrolled under part B, or both, and shall include—

"(A) the specific reasons for the determination (including, to the extent appropriate, a summary of the clinical or scientific evidence used in making the determination);

"(B) the procedures for obtaining additional information concerning the decision; and

"(C) notification of the right to appeal the decision and instructions on how to initiate such an appeal under this section.".

(4) SUBMISSION OF RECORD FOR APPEAL.—Section 1869(c)(3)(J)(i) (42 U.S.C. 1395ff(c)(3)(J)(i)) by striking "prepare" and inserting "submit" and by striking "with respect to" and all that follows through "and relevant policies".

(d) QUALIFIED INDEPENDENT CONTRACTORS.—

(1) ELIGIBILITY REQUIREMENTS OF QUALIFIED INDEPENDENT CONTRACTORS.—Section 1869(c)(3) (42 U.S.C. 1395ff(c)(3)), as amended by BIPA, is amended—

(A) in subparagraph (A), by striking "sufficient training and expertise in medical science and legal matters" and inserting "sufficient medical, legal, and other expertise (including knowledge of the program under this title) and sufficient staffing"; and

(B) by adding at the end the following new subparagraph:

"(K) INDEPENDENCE REQUIREMENTS.—

"(i) IN GENERAL.—Subject to clause (ii), a qualified independent contractor shall not conduct any activities in a case unless the entity—

"(I) is not a related party (as defined in subsection (g)(5));

"(II) does not have a material familial, financial, or professional relationship with such a party in relation to such case; and

"(III) does not otherwise have a conflict of interest with such a party.

"(ii) EXCEPTION FOR REASONABLE COMPENSATION.—Nothing in clause (i) shall be construed to prohibit receipt by a qualified independent contractor of compensation from the Secretary for the conduct of activities under this section if the compensation is provided consistent with clause (iii).

"(iii) LIMITATIONS ON ENTITY COMPENSATION.—Compensation provided by the Secretary to a qualified independent contractor in connection with reviews under this section shall not be contingent on any decision rendered by the contractor or by any reviewing professional.".

(2) ELIGIBILITY REQUIREMENTS FOR REVIEWERS.—Section 1869 (42 U.S.C. 1395ff), as amended by BIPA, is amended—

(A) by amending subsection (c)(3)(D) to read as follows:

"(D) QUALIFICATIONS FOR REVIEWERS.—The requirements of subsection (g) shall be met (relating to qualifications of reviewing professionals)."; and

(B) by adding at the end the following new subsection:

"(g) QUALIFICATIONS OF REVIEWERS.—

"(1) IN GENERAL.—In reviewing determinations under this section, a qualified independent contractor shall assure that—

"(A) each individual conducting a review shall meet the qualifications of paragraph (2);

"(B) compensation provided by the contractor to each such reviewer is consistent with paragraph (3); and

"(C) in the case of a review by a panel described in subsection (c)(3)(B) composed of physicians or other health care professionals (each in this subsection referred to as a 'reviewing professional'), a reviewing professional meets the qualifications described in paragraph (4) and, where a claim is regarding the furnishing of treatment by a physician (allopathic or osteopathic) or the provision of items or services by a physician (allopathic or osteopathic), a reviewing professional shall be a physician (allopathic or osteopathic).

"(2) INDEPENDENCE.—

"(A) IN GENERAL.—Subject to subparagraph (B), each individual conducting a review in a case shall—

"(i) not be a related party (as defined in paragraph (5));

"(ii) not have a material familial, financial, or professional relationship with such a party in the case under review; and

"(iii) not otherwise have a conflict of interest with such a party.

"(B) EXCEPTION.—Nothing in subparagraph (A) shall be construed to—

"(i) prohibit an individual, solely on the basis of a participation agreement with a fiscal intermediary, carrier, or other contractor, from serving as a reviewing professional if—

"(I) the individual is not involved in the provision of items or services in the case under review;

"(II) the fact of such an agreement is disclosed to the Secretary and the individual entitled to benefits under part A or enrolled under part B, or both, (or authorized representative) and neither party objects; and

"(III) the individual is not an employee of the intermediary, carrier, or contractor and does not provide services exclusively or primarily to or on behalf of such intermediary, carrier, or contractor;

"(ii) prohibit an individual who has staff privileges at the institution where the treatment involved takes place from serving as a reviewer merely on the basis of having such staff privileges if the existence of such privileges is disclosed to the Secretary and such individual (or authorized representative), and neither party objects; or

"(iii) prohibit receipt of compensation by a reviewing professional from a contractor if the compensation is provided consistent with paragraph (3).

For purposes of this paragraph, the term 'participation agreement' means an agreement relating to the provision of health care services by the individual and does not include the provision of services as a reviewer under this subsection.

"(3) LIMITATIONS ON REVIEWER COMPENSATION.—Compensation provided by a qualified independent contractor to a reviewer in connection with a review under this section shall not be contingent on the decision rendered by the reviewer.

"(4) LICENSURE AND EXPERTISE.—Each reviewing professional shall be—

"(A) a physician (allopathic or osteopathic) who is appropriately credentialed or licensed in one or more States to deliver health care services and has medical expertise in the field of practice that is appropriate for the items or services at issue; or

"(B) a health care professional who is legally authorized in one or more States (in accordance with State law or the State regulatory mechanism provided by State law) to furnish the health care items or services at issue and has medical expertise in the field of practice that is appropriate for such items or services.

"(5) RELATED PARTY DEFINED.—For purposes of this section, the term 'related party' means, with respect to a case under this title involving a specific individual entitled to benefits under part A or enrolled under part B, or both, any of the following:

"(A) The Secretary, the medicare administrative contractor involved, or any fiduciary, officer, director, or employee of the Department of Health and Human Services, or of such contractor.

"(B) The individual (or authorized representative).

"(C) The health care professional that provides the items or services involved in the case.

"(D) The institution at which the items or services (or treatment) involved in the case are provided.

"(E) The manufacturer of any drug or other item that is included in the items or services involved in the case.

"(F) Any other party determined under any regulations to have a substantial interest in the case involved.".

(3) REDUCING MINIMUM NUMBER OF QUALIFIED INDEPENDENT CONTRACTORS.—Section 1869(c)(4) (42 U.S.C. 1395ff(c)(4)) is amended by striking "not fewer than 12 qualified independent contractors under this subsection" and inserting "a sufficient number of qualified independent contractors (but not fewer than 4 such contractors) to conduct reconsiderations consistent with the timeframes applicable under this subsection".

(4) EFFECTIVE DATE.—The amendments made by paragraphs (1) and (2) shall be effective as if included in the enactment of the respective provisions of subtitle C of title V of BIPA, (114 Stat. 2763A–534).

(5) TRANSITION.—In applying section 1869(g) of the Social Security Act (as added by paragraph (2)), any reference to a medicare administrative contractor shall be deemed to include a reference to a fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and a carrier under section 1842 of such Act (42 U.S.C. 1395u).

SEC. 404. PREPAYMENT REVIEW.

(a) IN GENERAL.—Section 1874A, as added by section 201(a)(1) and as amended by sections 202(b), 301(b)(1), and 301(c)(1), is further amended by adding at the end the following new subsection:

"(h) CONDUCT OF PREPAYMENT REVIEW.—

"(1) CONDUCT OF RANDOM PREPAYMENT REVIEW.—

"(A) IN GENERAL.—A medicare administrative contractor may conduct random prepayment review only to develop a contractor-wide or program-wide claims payment error rates or under such additional circumstances as may be provided under regulations, developed in consultation with providers of services and suppliers.

"(B) USE OF STANDARD PROTOCOLS WHEN CONDUCTING PREPAYMENT REVIEWS.—When a medicare administrative contractor conducts a random prepayment review, the contractor may conduct such review only in accordance with a standard protocol for random prepayment audits developed by the Secretary.

"(C) CONSTRUCTION.—Nothing in this paragraph shall be construed as preventing the denial of payments for claims actually reviewed under a random prepayment review.

"(D) RANDOM PREPAYMENT REVIEW.—For purposes of this subsection, the term 'random prepayment review' means a demand for the production of records or documentation absent cause with respect to a claim.

"(2) LIMITATIONS ON NON-RANDOM PREPAYMENT REVIEW.—

"(A) LIMITATIONS ON INITIATION OF NON-RANDOM PREPAYMENT REVIEW.—A medicare administrative contractor may not initiate non-random prepayment review of a provider of services or supplier based on the initial identification by that provider of services or supplier of an improper billing practice unless there is a likelihood of sustained or high level of payment error (as defined in subsection (i)(3)(A)).

"(B) TERMINATION OF NON-RANDOM PREPAYMENT REVIEW.—The Secretary shall issue regulations relating to the termination, including termination dates, of non-random prepayment review. Such regulations may vary such a termination date based upon the differences in the circumstances triggering prepayment review.".

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in this subsection, the amendment made by subsection (a) shall take effect 1 year after the date of the enactment of this Act.

(2) DEADLINE FOR PROMULGATION OF CERTAIN REGULATIONS.—The Secretary shall first issue regulations under section 1874A(h) of the Social Security Act, as added by subsection (a), by not later than 1 year after the date of the enactment of this Act.

(3) APPLICATION OF STANDARD PROTOCOLS FOR RANDOM PREPAYMENT REVIEW.—Section 1874A(h)(1)(B) of the Social Security Act, as added by subsection (a), shall apply to random prepayment reviews conducted on or after such date (not later than 1 year after the date of the enactment of this Act) as the Secretary shall specify.

(c) APPLICATION TO FISCAL INTERMEDIARIES AND CARRIERS.—The provisions of section 1874A(h) of the Social Security Act, as added by subsection (a), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions.

SEC. 405. RECOVERY OF OVERPAYMENTS.

(a) IN GENERAL.—Section 1893 (42 U.S.C. 1395ddd) is amended by adding at the end the following new subsection:

"(f) RECOVERY OF OVERPAYMENTS.—

"(1) USE OF REPAYMENT PLANS.—

"(A) IN GENERAL.—If the repayment, within 30 days by a provider of services or supplier, of an overpayment under this title would constitute a hardship (as defined in subparagraph (B)), subject to subparagraph (C), upon request of the provider of services or supplier the Secretary shall enter into a plan with the provider of services or supplier for the repayment (through offset or otherwise) of such overpayment over a period of at least 6 months but not longer than 3 years (or not longer than 5 years in the case of extreme hardship, as determined by the Secretary). Interest shall accrue on the balance through the period of repayment. Such plan shall meet terms and conditions determined to be appropriate by the Secretary.

"(B) HARDSHIP.—

"(i) IN GENERAL.—For purposes of subparagraph (A), the repayment of an overpayment (or overpayments) within 30 days is deemed to constitute a hardship if—

"(I) in the case of a provider of services that files cost reports, the aggregate amount of the overpayments exceeds 10 percent of the amount paid under this title to the provider of services for the cost reporting period covered by the most recently submitted cost report; or

"(II) in the case of another provider of services or supplier, the aggregate amount of the overpayments exceeds 10 percent of the amount paid under this title to the provider of services or supplier for the previous calendar year.

"(ii) RULE OF APPLICATION.—The Secretary shall establish rules for the application of this subparagraph in the case of a provider of services or supplier that was not paid under this title during the previous year or was paid under this title only during a portion of that year.

"(iii) TREATMENT OF PREVIOUS OVERPAYMENTS.—If a provider of services or supplier has entered into a repayment plan under subparagraph (A) with respect to a specific overpayment amount, such payment amount under the repayment plan shall not be taken into account under clause (i) with respect to subsequent overpayment amounts.

"(C) EXCEPTIONS.—Subparagraph (A) shall not apply if—

"(i) the Secretary has reason to suspect that the provider of services or supplier may file for bankruptcy or otherwise cease to do business or discontinue participation in the program under this title; or

"(ii) there is an indication of fraud or abuse committed against the program.

"(D) IMMEDIATE COLLECTION IF VIOLATION OF REPAYMENT PLAN.—If a provider of services or supplier fails to make a payment in accordance with a repayment plan under this paragraph, the Secretary may immediately seek to offset or otherwise recover the total balance outstanding (including applicable interest) under the repayment plan.

"(E) RELATION TO NO FAULT PROVISION.—Nothing in this paragraph shall be construed as affecting the application of section 1870(c) (relating to no adjustment in the cases of certain overpayments).

"(2) LIMITATION ON RECOUPMENT.—

"(A) IN GENERAL.—In the case of a provider of services or supplier that is determined to have received an overpayment under this title and that seeks a reconsideration by a qualified independent contractor on such determination under section 1869(b)(1), the Secretary may not take any action (or authorize any other person, including any medicare contractor, as de-

fined in subparagraph (C)) to recoup the overpayment until the date the decision on the reconsideration has been rendered. If the provisions of section 1869(b)(1) (providing for such a reconsideration by a qualified independent contractor) are not in effect, in applying the previous sentence any reference to such a reconsideration shall be treated as a reference to a redetermination by the fiscal intermediary or carrier involved.

"(B) COLLECTION WITH INTEREST.—Insofar as the determination on such appeal is against the provider of services or supplier, interest on the overpayment shall accrue on and after the date of the original notice of overpayment. Insofar as such determination against the provider of services or supplier is later reversed, the Secretary shall provide for repayment of the amount recouped plus interest at the same rate as would apply under the previous sentence for the period in which the amount was recouped.

"(C) MEDICARE CONTRACTOR DEFINED.—For purposes of this subsection, the term 'medicare contractor' has the meaning given such term in section 1889(g).

"(3) LIMITATION ON USE OF EXTRAPOLATION.—A medicare contractor may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise unless—

"(A) there is a sustained or high level of payment error (as defined by the Secretary by regulation); or

"(B) documented educational intervention has failed to correct the payment error (as determined by the Secretary).

"(4) PROVISION OF SUPPORTING DOCUMENTATION.—In the case of a provider of services or supplier with respect to which amounts were previously overpaid, a medicare contractor may request the periodic production of records or supporting documentation for a limited sample of submitted claims to ensure that the previous practice is not continuing.

"(5) CONSENT SETTLEMENT REFORMS.—

"(A) IN GENERAL.—The Secretary may use a consent settlement (as defined in subparagraph (D)) to settle a projected overpayment.

"(B) OPPORTUNITY TO SUBMIT ADDITIONAL INFORMATION BEFORE CONSENT SETTLEMENT OFFER.—Before offering a provider of services or supplier a consent settlement, the Secretary shall—

"(i) communicate to the provider of services or supplier—

"(I) that, based on a review of the medical records requested by the Secretary, a preliminary evaluation of those records indicates that there would be an overpayment;

"(II) the nature of the problems identified in such evaluation; and

"(III) the steps that the provider of services or supplier should take to address the problems; and

"(ii) provide for a 45-day period during which the provider of services or supplier may furnish additional information concerning the medical records for the claims that had been reviewed.

"(C) CONSENT SETTLEMENT OFFER.—The Secretary shall review any additional information furnished by the provider of services or supplier under subparagraph (B)(ii). Taking into consideration such information, the Secretary shall determine if there still appears to be an overpayment. If so, the Secretary—

"(i) shall provide notice of such determination to the provider of services or supplier, including an explanation of the reason for such determination; and

"(ii) in order to resolve the overpayment, may offer the provider of services or supplier—

"(I) the opportunity for a statistically valid random sample; or

"(II) a consent settlement.

The opportunity provided under clause (ii)(I) does not waive any appeal rights with respect to the alleged overpayment involved.

"(D) CONSENT SETTLEMENT DEFINED.—For purposes of this paragraph, the term 'consent settlement' means an agreement between the Secretary and a provider of services or supplier whereby both parties agree to settle a projected overpayment based on less than a statistically valid sample of claims and the provider of services or supplier agrees not to appeal the claims involved.

"(6) NOTICE OF OVER-UTILIZATION OF CODES.—The Secretary shall establish, in consultation with organizations representing the classes of providers of services and suppliers, a process under which the Secretary provides for notice to classes of providers of services and suppliers served by the contractor in cases in which

the contractor has identified that particular billing codes may be overutilized by that class of providers of services or suppliers under the programs under this title (or provisions of title XI insofar as they relate to such programs).

"(7) PAYMENT AUDITS.—

"(A) WRITTEN NOTICE FOR POST-PAYMENT AUDITS.—Subject to subparagraph (C), if a medicare contractor decides to conduct a post-payment audit of a provider of services or supplier under this title, the contractor shall provide the provider of services or supplier with written notice (which may be in electronic form) of the intent to conduct such an audit.

"(B) EXPLANATION OF FINDINGS FOR ALL AUDITS.—Subject to subparagraph (C), if a medicare contractor audits a provider of services or supplier under this title, the contractor shall—

"(i) give the provider of services or supplier a full review and explanation of the findings of the audit in a manner that is understandable to the provider of services or supplier and permits the development of an appropriate corrective action plan;

"(ii) inform the provider of services or supplier of the appeal rights under this title as well as consent settlement options (which are at the discretion of the Secretary);

"(iii) give the provider of services or supplier an opportunity to provide additional information to the contractor; and

"(iv) take into account information provided, on a timely basis, by the provider of services or supplier under clause (iii).

"(C) EXCEPTION.—Subparagraphs (A) and (B) shall not apply if the provision of notice or findings would compromise pending law enforcement activities, whether civil or criminal, or reveal findings of law enforcement-related audits.

"(8) STANDARD METHODOLOGY FOR PROBE SAMPLING.—The Secretary shall establish a standard methodology for medicare contractors to use in selecting a sample of claims for review in the case of an abnormal billing pattern.".

(b) EFFECTIVE DATES AND DEADLINES.—

(1) USE OF REPAYMENT PLANS.—Section 1893(f)(1) of the Social Security Act, as added by subsection (a), shall apply to requests for repayment plans made after the date of the enactment of this Act.

(2) LIMITATION ON RECOUPMENT.—Section 1893(f)(2) of the Social Security Act, as added by subsection (a), shall apply to actions taken after the date of the enactment of this Act.

(3) USE OF EXTRAPOLATION.—Section 1893(f)(3) of the Social Security Act, as added by subsection (a), shall apply to statistically valid random samples initiated after the date that is 1 year after the date of the enactment of this Act.

(4) PROVISION OF SUPPORTING DOCUMENTATION.—Section 1893(f)(4) of the Social Security Act, as added by subsection (a), shall take effect on the date of the enactment of this Act.

(5) CONSENT SETTLEMENT.—Section 1893(f)(5) of the Social Security Act, as added by subsection (a), shall apply to consent settlements entered into after the date of the enactment of this Act.

(6) NOTICE OF OVERUTILIZATION.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall first establish the process for notice of overutilization of billing codes under section 1893A(f)(6) of the Social Security Act, as added by subsection (a).

(7) PAYMENT AUDITS.—Section 1893A(f)(7) of the Social Security Act, as added by subsection (a), shall apply to audits initiated after the date of the enactment of this Act.

(8) STANDARD FOR ABNORMAL BILLING PATTERNS.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall first establish a standard methodology for selection of sample claims for abnormal billing patterns under section 1893(f)(8) of the Social Security Act, as added by subsection (a).

SEC. 406. PROVIDER ENROLLMENT PROCESS; RIGHT OF APPEAL.

(a) IN GENERAL.—Section 1866 (42 U.S.C. 1395cc) is amended—

(1) by adding at the end of the heading the following: "; ENROLLMENT PROCESSES"; and

(2) by adding at the end the following new subsection:

"(j) ENROLLMENT PROCESS FOR PROVIDERS OF SERVICES AND SUPPLIERS.—

"(1) ENROLLMENT PROCESS.—

"(A) IN GENERAL.—The Secretary shall establish by regulation a process for the enrollment of providers of services and suppliers under this title.

"(B) DEADLINES.—The Secretary shall establish by regulation procedures under which there are deadlines for actions on applications for enrollment

(and, if applicable, renewal of enrollment). The Secretary shall monitor the performance of medicare administrative contractors in meeting the deadlines established under this subparagraph.

"(C) CONSULTATION BEFORE CHANGING PROVIDER ENROLLMENT FORMS.—The Secretary shall consult with providers of services and suppliers before making changes in the provider enrollment forms required of such providers and suppliers to be eligible to submit claims for which payment may be made under this title.

"(2) HEARING RIGHTS IN CASES OF DENIAL OR NON-RENEWAL.—A provider of services or supplier whose application to enroll (or, if applicable, to renew enrollment) under this title is denied may have a hearing and judicial review of such denial under the procedures that apply under subsection (h)(1)(A) to a provider of services that is dissatisfied with a determination by the Secretary.".

(b) EFFECTIVE DATES.—

(1) ENROLLMENT PROCESS.—The Secretary shall provide for the establishment of the enrollment process under section 1866(j)(1) of the Social Security Act, as added by subsection (a)(2), within 6 months after the date of the enactment of this Act.

(2) CONSULTATION.—Section 1866(j)(1)(C) of the Social Security Act, as added by subsection (a)(2), shall apply with respect to changes in provider enrollment forms made on or after January 1, 2004.

(3) HEARING RIGHTS.—Section 1866(j)(2) of the Social Security Act, as added by subsection (a)(2), shall apply to denials occurring on or after such date (not later than 1 year after the date of the enactment of this Act) as the Secretary specifies.

SEC. 407. PROCESS FOR CORRECTION OF MINOR ERRORS AND OMISSIONS WITHOUT PURSUING APPEALS PROCESS.

(a) CLAIMS.—The Secretary shall develop, in consultation with appropriate medicare contractors (as defined in section 1889(g) of the Social Security Act, as inserted by section 301(a)(1)) and representatives of providers of services and suppliers, a process whereby, in the case of minor errors or omissions (as defined by the Secretary) that are detected in the submission of claims under the programs under title XVIII of such Act, a provider of services or supplier is given an opportunity to correct such an error or omission without the need to initiate an appeal. Such process shall include the ability to resubmit corrected claims.

(b) PERMITTING USE OF CORRECTED AND SUPPLEMENTARY DATA.—

(1) IN GENERAL.—Section 1886(d)(10)(D)(vi) (42 U.S.C. 1395ww(d)(10)(D)(vi)) is amended by adding after subclause (II) at the end the following:

"Notwithstanding subclause (I), a hospital may submit, and the Secretary may accept upon verification, data that corrects or supplements the data described in such subclause without regard to whether the corrected or supplementary data relate to a cost report that has been settled.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to fiscal years beginning with fiscal year 2004.

(3) SUBMITTAL AND RESUBMITTAL OF APPLICATIONS PERMITTED FOR FISCAL YEAR 2004.—

(A) IN GENERAL.—Notwithstanding any other provision of law, a hospital may submit (or resubmit) an application for a change described in section 1886(d)(10)(C)(i)(II) of the Social Security Act for fiscal year 2004 if the hospital demonstrates on a timely basis to the satisfaction of the Secretary that the use of corrected or supplementary data under the amendment made by paragraph (1) would materially affect the approval of such an application.

(B) APPLICATION OF BUDGET NEUTRALITY.—If one or more hospital's applications are approved as a result of paragraph (1) and subparagraph (A) for fiscal year 2004, the Secretary shall make a proportional adjustment in the standardized amounts determined under section 1886(d)(3) of the Social Security Act (42 U.S.C. 1395ww(d)(3)) for fiscal year 2004 to assure that approval of such applications does not result in aggregate payments under section 1886(d) of such Act that are greater or less than those that would otherwise be made if paragraph (1) and subparagraph (A) did not apply.

SEC. 408. PRIOR DETERMINATION PROCESS FOR CERTAIN ITEMS AND SERVICES; ADVANCE BENEFICIARY NOTICES.

(a) IN GENERAL.—Section 1869 (42 U.S.C. 1395ff(b)), as amended by sections 521 and 522 of BIPA and section 403(d)(2)(B), is further amended by adding at the end the following new subsection:

"(h) PRIOR DETERMINATION PROCESS FOR CERTAIN ITEMS AND SERVICES.—

"(1) ESTABLISHMENT OF PROCESS.—

"(A) IN GENERAL.—With respect to a medicare administrative contractor that has a contract under section 1874A that provides for making payments under this title with respect to eligible items and services described in subparagraph (C), the Secretary shall establish a prior determination process that meets the requirements of this subsection and that shall be applied by such contractor in the case of eligible requesters.

"(B) ELIGIBLE REQUESTER.—For purposes of this subsection, each of the following shall be an eligible requester:

"(i) A physician, but only with respect to eligible items and services for which the physician may be paid directly.

"(ii) An individual entitled to benefits under this title, but only with respect to an item or service for which the individual receives, from the physician who may be paid directly for the item or service, an advance beneficiary notice under section 1879(a) that payment may not be made (or may no longer be made) for the item or service under this title.

"(C) ELIGIBLE ITEMS AND SERVICES.—For purposes of this subsection and subject to paragraph (2), eligible items and services are items and services which are physicians' services (as defined in paragraph (4)(A) of section 1848(f) for purposes of calculating the sustainable growth rate under such section).

"(2) SECRETARIAL FLEXIBILITY.—The Secretary shall establish by regulation reasonable limits on the categories of eligible items and services for which a prior determination of coverage may be requested under this subsection. In establishing such limits, the Secretary may consider the dollar amount involved with respect to the item or service, administrative costs and burdens, and other relevant factors.

"(3) REQUEST FOR PRIOR DETERMINATION.—

"(A) IN GENERAL.—Subject to paragraph (2), under the process established under this subsection an eligible requester may submit to the contractor a request for a determination, before the furnishing of an eligible item or service involved as to whether the item or service is covered under this title consistent with the applicable requirements of section 1862(a)(1)(A) (relating to medical necessity).

"(B) ACCOMPANYING DOCUMENTATION.—The Secretary may require that the request be accompanied by a description of the item or service, supporting documentation relating to the medical necessity for the item or service, and any other appropriate documentation. In the case of a request submitted by an eligible requester who is described in paragraph (1)(B)(ii), the Secretary may require that the request also be accompanied by a copy of the advance beneficiary notice involved.

"(4) RESPONSE TO REQUEST.—

"(A) IN GENERAL.—Under such process, the contractor shall provide the eligible requester with written notice of a determination as to whether—

"(i) the item or service is so covered;

"(ii) the item or service is not so covered; or

"(iii) the contractor lacks sufficient information to make a coverage determination.

If the contractor makes the determination described in clause (iii), the contractor shall include in the notice a description of the additional information required to make the coverage determination.

"(B) DEADLINE TO RESPOND.—Such notice shall be provided within the same time period as the time period applicable to the contractor providing notice of initial determinations on a claim for benefits under subsection (a)(2)(A).

"(C) INFORMING BENEFICIARY IN CASE OF PHYSICIAN REQUEST.—In the case of a request in which an eligible requester is not the individual described in paragraph (1)(B)(ii), the process shall provide that the individual to whom the item or service is proposed to be furnished shall be informed of any determination described in clause (ii) (relating to a determination of non-coverage) and the right (referred to in paragraph (6)(B)) to obtain the item or service and have a claim submitted for the item or service.

"(5) EFFECT OF DETERMINATIONS.—

"(A) BINDING NATURE OF POSITIVE DETERMINATION.—If the contractor makes the determination described in paragraph (4)(A)(i), such determination shall be binding on the contractor in the absence of fraud or evidence of misrepresentation of facts presented to the contractor.

"(B) NOTICE AND RIGHT TO REDETERMINATION IN CASE OF A DENIAL.—

"(i) IN GENERAL.—If the contractor makes the determination described in paragraph (4)(A)(ii)—

"(I) the eligible requester has the right to a redetermination by the contractor on the determination that the item or service is not so covered; and

"(II) the contractor shall include in notice under paragraph (4)(A) a brief explanation of the basis for the determination, including on what national or local coverage or noncoverage determination (if any) the determination is based, and the right to such a redetermination.

"(ii) DEADLINE FOR REDETERMINATIONS.—The contractor shall complete and provide notice of such redetermination within the same time period as the time period applicable to the contractor providing notice of redeterminations relating to a claim for benefits under subsection (a)(3)(C)(ii).

"(6) LIMITATION ON FURTHER REVIEW.—

"(A) IN GENERAL.—Contractor determinations described in paragraph (4)(A)(ii) or (4)(A)(iii) (and redeterminations made under paragraph (5)(B)), relating to pre-service claims are not subject to further administrative appeal or judicial review under this section or otherwise.

"(B) DECISION NOT TO SEEK PRIOR DETERMINATION OR NEGATIVE DETERMINATION DOES NOT IMPACT RIGHT TO OBTAIN SERVICES, SEEK REIMBURSEMENT, OR APPEAL RIGHTS.—Nothing in this subsection shall be construed as affecting the right of an individual who—

"(i) decides not to seek a prior determination under this subsection with respect to items or services; or

"(ii) seeks such a determination and has received a determination described in paragraph (4)(A)(ii),

from receiving (and submitting a claim for) such items services and from obtaining administrative or judicial review respecting such claim under the other applicable provisions of this section. Failure to seek a prior determination under this subsection with respect to items and services shall not be taken into account in such administrative or judicial review.

"(C) NO PRIOR DETERMINATION AFTER RECEIPT OF SERVICES.—Once an individual is provided items and services, there shall be no prior determination under this subsection with respect to such items or services.".

(b) EFFECTIVE DATE; TRANSITION.—

(1) EFFECTIVE DATE.—The Secretary shall establish the prior determination process under the amendment made by subsection (a) in such a manner as to provide for the acceptance of requests for determinations under such process filed not later than 18 months after the date of the enactment of this Act.

(2) TRANSITION.—During the period in which the amendment made by subsection (a) has become effective but contracts are not provided under section 1874A of the Social Security Act with medicare administrative contractors, any reference in section 1869(g) of such Act (as added by such amendment) to such a contractor is deemed a reference to a fiscal intermediary or carrier with an agreement under section 1816, or contract under section 1842, respectively, of such Act.

(3) LIMITATION ON APPLICATION TO SGR.—For purposes of applying section 1848(f)(2)(D) of the Social Security Act (42 U.S.C. 1395w–4(f)(2)(D)), the amendment made by subsection (a) shall not be considered to be a change in law or regulation.

(c) PROVISIONS RELATING TO ADVANCE BENEFICIARY NOTICES; REPORT ON PRIOR DETERMINATION PROCESS.—

(1) DATA COLLECTION.—The Secretary shall establish a process for the collection of information on the instances in which an advance beneficiary notice (as defined in paragraph (4)) has been provided and on instances in which a beneficiary indicates on such a notice that the beneficiary does not intend to seek to have the item or service that is the subject of the notice furnished.

(2) OUTREACH AND EDUCATION.—The Secretary shall establish a program of outreach and education for beneficiaries and providers of services and other persons on the appropriate use of advance beneficiary notices and coverage policies under the medicare program.

(3) GAO REPORT REPORT ON USE OF ADVANCE BENEFICIARY NOTICES.—Not later than 18 months after the date on which section 1869(g) of the Social Security Act (as added by subsection (a)) takes effect, the Comptroller General of the United States shall submit to Congress a report on the use of advance beneficiary notices under title XVIII of such Act. Such report shall include information concerning the providers of services and other persons that have provided such notices and the response of beneficiaries to such notices.

(4) GAO REPORT ON USE OF PRIOR DETERMINATION PROCESS.—Not later than 18 months after the date on which section 1869(g) of the Social Security Act (as added by subsection (a)) takes effect, the Comptroller General of the United States shall submit to Congress a report on the use of the prior determination process under such section. Such report shall include—

(A) information concerning the types of procedures for which a prior determination has been sought, determinations made under the process, and changes in receipt of services resulting from the application of such process; and

(B) an evaluation of whether the process was useful for physicians (and other suppliers) and beneficiaries, whether it was timely, and whether the amount of information required was burdensome to physicians and beneficiaries.

(5) ADVANCE BENEFICIARY NOTICE DEFINED.—In this subsection, the term "advance beneficiary notice" means a written notice provided under section 1879(a) of the Social Security Act (42 U.S.C. 1395pp(a)) to an individual entitled to benefits under part A or B of title XVIII of such Act before items or services are furnished under such part in cases where a provider of services or other person that would furnish the item or service believes that payment will not be made for some or all of such items or services under such title.

TITLE V—MISCELLANEOUS PROVISIONS

SEC. 501. POLICY DEVELOPMENT REGARDING EVALUATION AND MANAGEMENT (E & M) DOCUMENTATION GUIDELINES.

(a) IN GENERAL.—The Secretary may not implement any new documentation guidelines for, or clinical examples of, evaluation and management physician services under the title XVIII of the Social Security Act on or after the date of the enactment of this Act unless the Secretary—

(1) has developed the guidelines in collaboration with practicing physicians (including both generalists and specialists) and provided for an assessment of the proposed guidelines by the physician community;

(2) has established a plan that contains specific goals, including a schedule, for improving the use of such guidelines;

(3) has conducted appropriate and representative pilot projects under subsection (b) to test modifications to the evaluation and management documentation guidelines;

(4) finds that the objectives described in subsection (c) will be met in the implementation of such guidelines; and

(5) has established, and is implementing, a program to educate physicians on the use of such guidelines and that includes appropriate outreach.

The Secretary shall make changes to the manner in which existing evaluation and management documentation guidelines are implemented to reduce paperwork burdens on physicians.

(b) PILOT PROJECTS TO TEST EVALUATION AND MANAGEMENT DOCUMENTATION GUIDELINES.—

(1) IN GENERAL.—The Secretary shall conduct under this subsection appropriate and representative pilot projects to test new evaluation and management documentation guidelines referred to in subsection (a).

(2) LENGTH AND CONSULTATION.—Each pilot project under this subsection shall—

(A) be voluntary;

(B) be of sufficient length as determined by the Secretary to allow for preparatory physician and medicare contractor education, analysis, and use and assessment of potential evaluation and management guidelines; and

(C) be conducted, in development and throughout the planning and operational stages of the project, in consultation with practicing physicians (including both generalists and specialists).

(3) RANGE OF PILOT PROJECTS.—Of the pilot projects conducted under this subsection—

(A) at least one shall focus on a peer review method by physicians (not employed by a medicare contractor) which evaluates medical record information for claims submitted by physicians identified as statistical outliers relative to definitions published in the Current Procedures Terminology (CPT) code book of the American Medical Association;

(B) at least one shall focus on an alternative method to detailed guidelines based on physician documentation of face to face encounter time with a patient;

(C) at least one shall be conducted for services furnished in a rural area and at least one for services furnished outside such an area; and

(D) at least one shall be conducted in a setting where physicians bill under physicians' services in teaching settings and at least one shall be conducted in a setting other than a teaching setting.

(4) BANNING OF TARGETING OF PILOT PROJECT PARTICIPANTS.—Data collected under this subsection shall not be used as the basis for overpayment demands or post-payment audits. Such limitation applies only to claims filed as part of the pilot project and lasts only for the duration of the pilot project and only as long as the provider is a participant in the pilot project.

(5) STUDY OF IMPACT.—Each pilot project shall examine the effect of the new evaluation and management documentation guidelines on—

(A) different types of physician practices, including those with fewer than 10 full-time-equivalent employees (including physicians); and

(B) the costs of physician compliance, including education, implementation, auditing, and monitoring.

(6) PERIODIC REPORTS.—The Secretary shall submit to Congress periodic reports on the pilot projects under this subsection.

(c) OBJECTIVES FOR EVALUATION AND MANAGEMENT GUIDELINES.—The objectives for modified evaluation and management documentation guidelines developed by the Secretary shall be to—

(1) identify clinically relevant documentation needed to code accurately and assess coding levels accurately;

(2) decrease the level of non-clinically pertinent and burdensome documentation time and content in the physician's medical record;

(3) increase accuracy by reviewers; and

(4) educate both physicians and reviewers.

(d) STUDY OF SIMPLER, ALTERNATIVE SYSTEMS OF DOCUMENTATION FOR PHYSICIAN CLAIMS.—

(1) STUDY.—The Secretary shall carry out a study of the matters described in paragraph (2).

(2) MATTERS DESCRIBED.—The matters referred to in paragraph (1) are—

(A) the development of a simpler, alternative system of requirements for documentation accompanying claims for evaluation and management physician services for which payment is made under title XVIII of the Social Security Act; and

(B) consideration of systems other than current coding and documentation requirements for payment for such physician services.

(3) CONSULTATION WITH PRACTICING PHYSICIANS.—In designing and carrying out the study under paragraph (1), the Secretary shall consult with practicing physicians, including physicians who are part of group practices and including both generalists and specialists.

(4) APPLICATION OF HIPAA UNIFORM CODING REQUIREMENTS.—In developing an alternative system under paragraph (2), the Secretary shall consider requirements of administrative simplification under part C of title XI of the Social Security Act.

(5) REPORT TO CONGRESS.—(A) Not later than October 1, 2005, the Secretary shall submit to Congress a report on the results of the study conducted under paragraph (1).

(B) The Medicare Payment Advisory Commission shall conduct an analysis of the results of the study included in the report under subparagraph (A) and shall submit a report on such analysis to Congress.

(e) STUDY ON APPROPRIATE CODING OF CERTAIN EXTENDED OFFICE VISITS.—The Secretary shall conduct a study of the appropriateness of coding in cases of extended office visits in which there is no diagnosis made. Not later than October 1, 2005, the Secretary shall submit a report to Congress on such study and shall include recommendations on how to code appropriately for such visits in a manner that takes into account the amount of time the physician spent with the patient.

(f) DEFINITIONS.—In this section—

(1) the term "rural area" has the meaning given that term in section 1886(d)(2)(D) of the Social Security Act, 42 U.S.C. 1395ww(d)(2)(D); and

(2) the term "teaching settings" are those settings described in section 415.150 of title 42, Code of Federal Regulations.

SEC. 502. IMPROVEMENT IN OVERSIGHT OF TECHNOLOGY AND COVERAGE.

(a) COUNCIL FOR TECHNOLOGY AND INNOVATION.—Section 1868 (42 U.S.C. 1395ee), as amended by section 301(a), is amended by adding at the end the following new subsection:

"(c) COUNCIL FOR TECHNOLOGY AND INNOVATION.—

"(1) ESTABLISHMENT.—The Secretary shall establish a Council for Technology and Innovation within the Centers for Medicare & Medicaid Services (in this section referred to as 'CMS').

"(2) COMPOSITION.—The Council shall be composed of senior CMS staff and clinicians and shall be chaired by the Executive Coordinator for Technology and Innovation (appointed or designated under paragraph (4)).

"(3) DUTIES.—The Council shall coordinate the activities of coverage, coding, and payment processes under this title with respect to new technologies and procedures, including new drug therapies, and shall coordinate the exchange of information on new technologies between CMS and other entities that make similar decisions.

"(4) EXECUTIVE COORDINATOR FOR TECHNOLOGY AND INNOVATION.—The Secretary shall appoint (or designate) a noncareer appointee (as defined in section 3132(a)(7) of title 5, United States Code) who shall serve as the Executive Coordinator for Technology and Innovation. Such executive coordinator shall report to the Administrator of CMS, shall chair the Council, shall oversee the execution of its duties, and shall serve as a single point of contact for outside groups and entities regarding the coverage, coding, and payment processes under this title.".

(b) METHODS FOR DETERMINING PAYMENT BASIS FOR NEW LAB TESTS.—Section 1833(h) (42 U.S.C. 1395l(h)) is amended by adding at the end the following:

"(8)(A) The Secretary shall establish by regulation procedures for determining the basis for, and amount of, payment under this subsection for any clinical diagnostic laboratory test with respect to which a new or substantially revised HCPCS code is assigned on or after January 1, 2005 (in this paragraph referred to as 'new tests').

"(B) Determinations under subparagraph (A) shall be made only after the Secretary—

"(i) makes available to the public (through an Internet site and other appropriate mechanisms) a list that includes any such test for which establishment of a payment amount under this subsection is being considered for a year;

"(ii) on the same day such list is made available, causes to have published in the Federal Register notice of a meeting to receive comments and recommendations (and data on which recommendations are based) from the public on the appropriate basis under this subsection for establishing payment amounts for the tests on such list;

"(iii) not less than 30 days after publication of such notice convenes a meeting, that includes representatives of officials of the Centers for Medicare & Medicaid Services involved in determining payment amounts, to receive such comments and recommendations (and data on which the recommendations are based);

"(iv) taking into account the comments and recommendations (and accompanying data) received at such meeting, develops and makes available to the public (through an Internet site and other appropriate mechanisms) a list of proposed determinations with respect to the appropriate basis for establishing a payment amount under this subsection for each such code, together with an explanation of the reasons for each such determination, the data on which the determinations are based, and a request for public written comments on the proposed determination; and

"(v) taking into account the comments received during the public comment period, develops and makes available to the public (through an Internet site and other appropriate mechanisms) a list of final determinations of the payment amounts for such tests under this subsection, together with the rationale for each such determination, the data on which the determinations are based, and responses to comments and suggestions received from the public.

"(C) Under the procedures established pursuant to subparagraph (A), the Secretary shall—

"(i) set forth the criteria for making determinations under subparagraph (A); and

"(ii) make available to the public the data (other than proprietary data) considered in making such determinations.

"(D) The Secretary may convene such further public meetings to receive public comments on payment amounts for new tests under this subsection as the Secretary deems appropriate.

"(E) For purposes of this paragraph:

"(i) The term 'HCPCS' refers to the Health Care Procedure Coding System.

"(ii) A code shall be considered to be 'substantially revised' if there is a substantive change to the definition of the test or procedure to which the code applies (such as a new analyte or a new methodology for measuring an existing analyte-specific test).".

(c) GAO STUDY ON IMPROVEMENTS IN EXTERNAL DATA COLLECTION FOR USE IN THE MEDICARE INPATIENT PAYMENT SYSTEM.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study that analyzes which external data can be collected in a shorter time frame by the Centers for Medicare & Medicaid Services for use in computing payments for inpatient hospital services. The study may include an evaluation of the feasibility and appropriateness of using of quarterly samples or special surveys or any other methods. The study shall include an analysis of whether other executive agencies, such as the Bureau of Labor Statistics in the Department of Commerce, are best suited to collect this information.

(2) REPORT.—By not later than October 1, 2004, the Comptroller General shall submit a report to Congress on the study under paragraph (1).

(d) PROCESS FOR ADOPTION OF ICD CODES AS DATA STANDARD.—Section 1172(f) (42 U.S.C. 1320d–1(f)) is amended by inserting after the first sentence the following: "Notwithstanding the preceding sentence, if the National Committee on Vital and Health Statistics has not made a recommendation to the Secretary before the date of the enactment of this sentence, with respect to the adoption of the International Classification of Diseases, 10th Revision, Procedure Coding System ('ICD–10–PCS') and the International Classification of Diseases, 10th Revision, Clinical Modification ('ICD–10–CM') as a standard under this part for the reporting of services, the Secretary may adopt ICD–10–PCS and ICD–10–CM as such a standard on or after such date without receiving such a recommendation.".

SEC. 503. TREATMENT OF HOSPITALS FOR CERTAIN SERVICES UNDER MEDICARE SECONDARY PAYOR (MSP) PROVISIONS.

(a) IN GENERAL.—The Secretary shall not require a hospital (including a critical access hospital) to ask questions (or obtain information) relating to the application of section 1862(b) of the Social Security Act (relating to medicare secondary payor provisions) in the case of reference laboratory services described in subsection (b), if the Secretary does not impose such requirement in the case of such services furnished by an independent laboratory.

(b) REFERENCE LABORATORY SERVICES DESCRIBED.—Reference laboratory services described in this subsection are clinical laboratory diagnostic tests (or the interpretation of such tests, or both) furnished without a face-to-face encounter between the individual entitled to benefits under part A or enrolled under part B, or both, and the hospital involved and in which the hospital submits a claim only for such test or interpretation.

SEC. 504. EMTALA IMPROVEMENTS.

(a) PAYMENT FOR EMTALA-MANDATED SCREENING AND STABILIZATION SERVICES.—

(1) IN GENERAL.—Section 1862 (42 U.S.C. 1395y) is amended by inserting after subsection (c) the following new subsection:

"(d) For purposes of subsection (a)(1)(A), in the case of any item or service that is required to be provided pursuant to section 1867 to an individual who is entitled to benefits under this title, determinations as to whether the item or service is reasonable and necessary shall be made on the basis of the information available to the treating physician or practitioner (including the patient's presenting symptoms or complaint) at the time the item or service was ordered or furnished by the physician or practitioner (and not on the patient's principal diagnosis). When making such determinations with respect to such an item or service, the Secretary shall not consider the frequency with which the item or service was provided to the patient before or after the time of the admission or visit.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to items and services furnished on or after January 1, 2004.

(b) NOTIFICATION OF PROVIDERS WHEN EMTALA INVESTIGATION CLOSED.—Section 1867(d) (42 U.S.C. 42 U.S.C. 1395dd(d)) is amended by adding at the end the following new paragraph:

"(4) NOTICE UPON CLOSING AN INVESTIGATION.—The Secretary shall establish a procedure to notify hospitals and physicians when an investigation under this section is closed.".

(c) PRIOR REVIEW BY PEER REVIEW ORGANIZATIONS IN EMTALA CASES INVOLVING TERMINATION OF PARTICIPATION.—

(1) IN GENERAL.—Section 1867(d)(3) (42 U.S.C. 1395dd(d)(3)) is amended—

(A) in the first sentence, by inserting "or in terminating a hospital's participation under this title" after "in imposing sanctions under paragraph (1)"; and

(B) by adding at the end the following new sentences: "Except in the case in which a delay would jeopardize the health or safety of individuals, the Secretary shall also request such a review before making a compliance de-

termination as part of the process of terminating a hospital's participation under this title for violations related to the appropriateness of a medical screening examination, stabilizing treatment, or an appropriate transfer as required by this section, and shall provide a period of 5 days for such review. The Secretary shall provide a copy of the organization's report to the hospital or physician consistent with confidentiality requirements imposed on the organization under such part B.".

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to terminations of participation initiated on or after the date of the enactment of this Act.

SEC. 505. EMERGENCY MEDICAL TREATMENT AND ACTIVE LABOR ACT (EMTALA) TECHNICAL ADVISORY GROUP.

(a) ESTABLISHMENT.—The Secretary shall establish a Technical Advisory Group (in this section referred to as the "Advisory Group") to review issues related to the Emergency Medical Treatment and Labor Act (EMTALA) and its implementation. In this section, the term "EMTALA" refers to the provisions of section 1867 of the Social Security Act (42 U.S.C. 1395dd).

(b) MEMBERSHIP.—The Advisory Group shall be composed of 19 members, including the Administrator of the Centers for Medicare & Medicaid Services and the Inspector General of the Department of Health and Human Services and of which—

(1) 4 shall be representatives of hospitals, including at least one public hospital, that have experience with the application of EMTALA and at least 2 of which have not been cited for EMTALA violations;

(2) 7 shall be practicing physicians drawn from the fields of emergency medicine, cardiology or cardiothoracic surgery, orthopedic surgery, neurosurgery, pediatrics or a pediatric subspecialty, obstetrics-gynecology, and psychiatry, with not more than one physician from any particular field;

(3) 2 shall represent patients;

(4) 2 shall be staff involved in EMTALA investigations from different regional offices of the Centers for Medicare & Medicaid Services; and

(5) 1 shall be from a State survey office involved in EMTALA investigations and 1 shall be from a peer review organization, both of whom shall be from areas other than the regions represented under paragraph (4).

In selecting members described in paragraphs (1) through (3), the Secretary shall consider qualified individuals nominated by organizations representing providers and patients.

(c) GENERAL RESPONSIBILITIES.—The Advisory Group—

(1) shall review EMTALA regulations;

(2) may provide advice and recommendations to the Secretary with respect to those regulations and their application to hospitals and physicians;

(3) shall solicit comments and recommendations from hospitals, physicians, and the public regarding the implementation of such regulations; and

(4) may disseminate information on the application of such regulations to hospitals, physicians, and the public.

(d) ADMINISTRATIVE MATTERS.—

(1) CHAIRPERSON.—The members of the Advisory Group shall elect a member to serve as chairperson of the Advisory Group for the life of the Advisory Group.

(2) MEETINGS.—The Advisory Group shall first meet at the direction of the Secretary. The Advisory Group shall then meet twice per year and at such other times as the Advisory Group may provide.

(e) TERMINATION.—The Advisory Group shall terminate 30 months after the date of its first meeting.

(f) WAIVER OF ADMINISTRATIVE LIMITATION.—The Secretary shall establish the Advisory Group notwithstanding any limitation that may apply to the number of advisory committees that may be established (within the Department of Health and Human Services or otherwise).

SEC. 506. AUTHORIZING USE OF ARRANGEMENTS TO PROVIDE CORE HOSPICE SERVICES IN CERTAIN CIRCUMSTANCES.

(a) IN GENERAL.—Section 1861(dd)(5) (42 U.S.C. 1395x(dd)(5)) is amended by adding at the end the following:

"(D) In extraordinary, exigent, or other non-routine circumstances, such as unanticipated periods of high patient loads, staffing shortages due to illness or other events, or temporary travel of a patient outside a hospice program's service area, a hospice program may enter into arrangements with another hospice program for the provision by that other program of services described in paragraph (2)(A)(ii)(I). The provisions of paragraph (2)(A)(ii)(II) shall apply with respect to the services provided under such arrangements.

"(E) A hospice program may provide services described in paragraph (1)(A) other than directly by the program if the services are highly specialized services of a registered professional nurse and are provided non-routinely and so infrequently so that the provision of such services directly would be impracticable and prohibitively expensive.".

(b) CONFORMING PAYMENT PROVISION.—Section 1814(i) (42 U.S.C. 1395f(i)) is amended by adding at the end the following new paragraph:

"(4) In the case of hospice care provided by a hospice program under arrangements under section 1861(dd)(5)(D) made by another hospice program, the hospice program that made the arrangements shall bill and be paid for the hospice care.".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to hospice care provided on or after the date of the enactment of this Act.

SEC. 507. APPLICATION OF OSHA BLOODBORNE PATHOGENS STANDARD TO CERTAIN HOSPITALS.

(a) IN GENERAL.—Section 1866 (42 U.S.C. 1395cc) is amended—

(1) in subsection (a)(1)—

(A) in subparagraph (R), by striking "and" at the end;

(B) in subparagraph (S), by striking the period at the end and inserting ", and"; and

(C) by inserting after subparagraph (S) the following new subparagraph:

"(T) in the case of hospitals that are not otherwise subject to the Occupational Safety and Health Act of 1970 or a State occupational safety and health plan that is approved under section 18(b) of such Act, to comply with the Bloodborne Pathogens standard under section 1910.1030 of title 29 of the Code of Federal Regulations (or as subsequently redesignated).."; and

(2) by adding at the end of subsection (b) the following new paragraph:

"(4)(A) A hospital that fails to comply with the requirement of subsection (a)(1)(T) (relating to the Bloodborne Pathogens standard) is subject to a civil money penalty in an amount described in subparagraph (B), but is not subject to termination of an agreement under this section.

"(B) The amount referred to in subparagraph (A) is an amount that is similar to the amount of civil penalties that may be imposed under section 17 of the Occupational Safety and Health Act of 1970 for a violation of the Bloodborne Pathogens standard referred to in subsection (a)(1)(T) by a hospital that is subject to the provisions of such Act.

"(C) A civil money penalty under this paragraph shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A are imposed and collected under that section.".

(b) EFFECTIVE DATE.—The amendments made by this subsection (a) shall apply to hospitals as of July 1, 2004.

SEC. 508. BIPA-RELATED TECHNICAL AMENDMENTS AND CORRECTIONS.

(a) TECHNICAL AMENDMENTS RELATING TO ADVISORY COMMITTEE UNDER BIPA SECTION 522.—(1) Subsection (i) of section 1114 (42 U.S.C. 1314)—

(A) is transferred to section 1862 and added at the end of such section; and

(B) is redesignated as subsection (j).

(2) Section 1862 (42 U.S.C. 1395y) is amended—

(A) in the last sentence of subsection (a), by striking "established under section 1114(f)"; and

(B) in subsection (j), as so transferred and redesignated—

(i) by striking "under subsection (f)"; and

(ii) by striking "section 1862(a)(1)" and inserting "subsection (a)(1)".

(b) TERMINOLOGY CORRECTIONS.—(1) Section 1869(c)(3)(I)(ii) (42 U.S.C. 1395ff(c)(3)(I)(ii)), as amended by section 521 of BIPA, is amended—

(A) in subclause (III), by striking "policy" and inserting "determination"; and

(B) in subclause (IV), by striking "medical review policies" and inserting "coverage determinations".

(2) Section 1852(a)(2)(C) (42 U.S.C. 1395w–22(a)(2)(C)) is amended by striking "policy" and "POLICY" and inserting "determination" each place it appears and "DETERMINATION", respectively.

(c) REFERENCE CORRECTIONS.—Section 1869(f)(4) (42 U.S.C. 1395ff(f)(4)), as added by section 522 of BIPA, is amended—

(1) in subparagraph (A)(iv), by striking "subclause (I), (II), or (III)" and inserting "clause (i), (ii), or (iii)";

(2) in subparagraph (B), by striking "clause (i)(IV)" and "clause (i)(III)" and inserting "subparagraph (A)(iv)" and "subparagraph (A)(iii)", respectively; and

(3) in subparagraph (C), by striking "clause (i)", "subclause (IV)" and "subparagraph (A)" and inserting "subparagraph (A)", "clause (iv)" and "paragraph (1)(A)", respectively each place it appears.

(d) OTHER CORRECTIONS.—Effective as if included in the enactment of section 521(c) of BIPA, section 1154(e) (42 U.S.C. 1320c–3(e)) is amended by striking paragraph (5).

(e) EFFECTIVE DATE.—Except as otherwise provided, the amendments made by this section shall be effective as if included in the enactment of BIPA.

SEC. 509. CONFORMING AUTHORITY TO WAIVE A PROGRAM EXCLUSION.

The first sentence of section 1128(c)(3)(B) (42 U.S.C. 1320a–7(c)(3)(B)) is amended to read as follows: "Subject to subparagraph (G), in the case of an exclusion under subsection (a), the minimum period of exclusion shall be not less than five years, except that, upon the request of the administrator of a Federal health care program (as defined in section 1128B(f)) who determines that the exclusion would impose a hardship on individuals entitled to benefits under part A of title XVIII or enrolled under part B of such title, or both, the Secretary may waive the exclusion under subsection (a)(1), (a)(3), or (a)(4) with respect to that program in the case of an individual or entity that is the sole community physician or sole source of essential specialized services in a community.".

SEC. 510. TREATMENT OF CERTAIN DENTAL CLAIMS.

(a) IN GENERAL.—Section 1862 (42 U.S.C. 1395y), as amended by section 508(a)(1), is amended by adding at the end the following new subsection:

"(k)(1) Subject to paragraph (2), a group health plan (as defined in subsection (a)(1)(A)(v)) providing supplemental or secondary coverage to individuals also entitled to services under this title shall not require a medicare claims determination under this title for dental benefits specifically excluded under subsection (a)(12) as a condition of making a claims determination for such benefits under the group health plan.

"(2) A group health plan may require a claims determination under this title in cases involving or appearing to involve inpatient dental hospital services or dental services expressly covered under this title pursuant to actions taken by the Secretary.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on the date that is 60 days after the date of the enactment of this Act.

SEC. 511. FURNISHING HOSPITALS WITH INFORMATION TO COMPUTE DSH FORMULA.

Beginning not later than 1 year after the date of the enactment of this Act, the Secretary shall furnish to subsection (d) hospitals (as defined in section 1886(d)(1)(B) of the Social Security Act, 42 U.S.C. 1395ww(d)(1)(B)) the data necessary for such hospitals to compute the number of patient days described in subclause (II) of section 1886(d)(5)(F)(vi) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(F)(vi)) used in computing the disproportionate patient percentage under such section for that hospital. Such data shall also be furnished to other hospitals which would qualify for additional payments under part A of title XVIII of the Social Security Act on the basis of such data.

SEC. 512. REVISIONS TO REASSIGNMENT PROVISIONS.

(a) IN GENERAL.—Section 1842(b)(6)(A)(ii) (42 U.S.C. 1395u(b)(6)(A)(ii)) is amended to read as follows: "(ii) where the service was provided under a contractual arrangement between such physician or other person and a qualified entity (as defined by the Secretary) or other person, to the entity or other person if under such arrangement such entity or individual submits the bill for such service and such arrangement (I) includes joint and several liability for overpayment by such physician or other person and such entity or other person, and (II) meets such other program integrity and other safeguards as the Secretary may determine to be appropriate,".

(b) CONFORMING AMENDMENT.—The second sentence of section 1842(b)(6) (42 U.S.C. 1395u(b)(6)) is amended by striking "except to an employer or facility as described in clause (A)" and inserting "except to an employer, entity, or other person as described in subparagraph (A)".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to payments made on or after one year after the date of the enactment of this Act.

SEC. 513. SPECIALIZED MEDICARE+CHOICE PLANS FOR SPECIAL NEEDS BENEFICIARIES.

(a) TREATMENT AS COORDINATED CARE PLAN.—Section 1851(a)(2)(A) (42 U.S.C. 1395w–21(a)(2)(A)) is amended by adding at the end the following new sentence: "Specialized Medicare+Choice plans for special needs beneficiaries (as defined in section 1859(b)(4)) may be any type of coordinated care plan.".

(b) SPECIALIZED MEDICARE+CHOICE PLAN FOR SPECIAL NEEDS BENEFICIARIES DEFINED.—Section 1859(b) (42 U.S.C. 1395w–29(b)) is amended by adding at the end the following new paragraph:

"(4) SPECIALIZED MEDICARE+CHOICE PLANS FOR SPECIAL NEEDS BENEFICIARIES.—

"(A) IN GENERAL.—The term 'specialized Medicare+Choice plan for special needs beneficiaries' means a Medicare+Choice plan that exclusively serves special needs beneficiaries (as defined in subparagraph (B)).

"(B) SPECIAL NEEDS BENEFICIARY.—The term 'special needs beneficiary' means a Medicare+Choice eligible individual who—

"(i) is institutionalized (as defined by the Secretary);

"(ii) is entitled to medical assistance under a State plan under title XIX; or

"(iii) meets such requirements as the Secretary may determine would benefit from enrollment in such a specialized Medicare+Choice plan described in subparagraph (A) for individuals with severe or disabling chronic conditions.".

(c) RESTRICTION ON ENROLLMENT PERMITTED.—Section 1859 (42 U.S.C. 1395w–29) is amended by adding at the end the following new subsection:

"(f) RESTRICTION ON ENROLLMENT FOR SPECIALIZED MEDICARE+CHOICE PLANS FOR SPECIAL NEEDS BENEFICIARIES.—In the case of a specialized Medicare+Choice plan (as defined in subsection (b)(4)), notwithstanding any other provision of this part and in accordance with regulations of the Secretary and for periods before January 1, 2008, the plan may restrict the enrollment of individuals under the plan to individuals who are within one or more classes of special needs beneficiaries.".

(d) REPORT TO CONGRESS.—Not later than December 31, 2006, the Secretary shall submit to Congress a report that assesses the impact of specialized Medicare+Choice plans for special needs beneficiaries on the cost and quality of services provided to enrollees. Such report shall include an assessment of the costs and savings to the medicare program as a result of amendments made by subsections (a), (b), and (c).

(e) EFFECTIVE DATES.—

(1) IN GENERAL.—The amendments made by subsections (a), (b), and (c) shall take effect upon the date of the enactment of this Act.

(2) DEADLINE FOR ISSUANCE OF REQUIREMENTS FOR SPECIAL NEEDS BENEFICIARIES; TRANSITION.—No later than 6 months after the date of the enactment of this Act, the Secretary shall issue final regulations to establish requirements for special needs beneficiaries under section 1859(b)(4)(B)(iii) of the Social Security Act, as added by subsection (b).

SEC. 514. TEMPORARY SUSPENSION OF OASIS REQUIREMENT FOR COLLECTION OF DATA ON NON-MEDICARE AND NON-MEDICAID PATIENTS.

(a) IN GENERAL.—During the period described in subsection (b), the Secretary may not require, under section 4602(e) of the Balanced Budget Act of 1997 or otherwise under OASIS, a home health agency to gather or submit information that relates to an individual who is not eligible for benefits under either title XVIII or title XIX of the Social Security Act (such information in this section referred to as "non-medicare/medicaid OASIS information").

(b) PERIOD OF SUSPENSION.—The period described in this subsection—

(1) begins on the date of the enactment of this Act; and

(2) ends on the last day of the 2nd month beginning after the date as of which the Secretary has published final regulations regarding the collection and use by the Centers for Medicare & Medicaid Services of non-medicare/medicaid OASIS information following the submission of the report required under subsection (c).

(c) REPORT.—

(1) STUDY.—The Secretary shall conduct a study on how non-medicare/medicaid OASIS information is and can be used by large home health agencies. Such study shall examine—

(A) whether there are unique benefits from the analysis of such information that cannot be derived from other information available to, or collected by, such agencies; and

(B) the value of collecting such information by small home health agencies compared to the administrative burden related to such collection.

In conducting the study the Secretary shall obtain recommendations from quality assessment experts in the use of such information and the necessity of small, as well as large, home health agencies collecting such information.

(2) REPORT.—The Secretary shall submit to Congress a report on the study conducted under paragraph (1) by not later than 18 months after the date of the enactment of this Act.

(d) CONSTRUCTION.—Nothing in this section shall be construed as preventing home health agencies from collecting non-medicare/medicaid OASIS information for their own use.

SEC. 515. MISCELLANEOUS REPORTS, STUDIES, AND PUBLICATION REQUIREMENTS.

(a) GAO REPORTS ON THE PHYSICIAN COMPENSATION.—

(1) SUSTAINABLE GROWTH RATE AND UPDATES.—Not later than 6 months after the date of the enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on the appropriateness of the updates in the conversion factor under subsection (d)(3) of section 1848 of the Social Security Act (42 U.S.C. 1395w–4), including the appropriateness of the sustainable growth rate formula under subsection (f) of such section for 2002 and succeeding years. Such report shall examine the stability and predictability of such updates and rate and alternatives for the use of such rate in the updates.

(2) PHYSICIAN COMPENSATION GENERALLY.—Not later than 12 months after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report on all aspects of physician compensation for services furnished under title XVIII of the Social Security Act, and how those aspects interact and the effect on appropriate compensation for physician services. Such report shall review alternatives for the physician fee schedule under section 1848 of such title (42 U.S.C. 1395w–4).

(b) ANNUAL PUBLICATION OF LIST OF NATIONAL COVERAGE DETERMINATIONS.—The Secretary shall provide, in an appropriate annual publication available to the public, a list of national coverage determinations made under title XVIII of the Social Security Act in the previous year and information on how to get more information with respect to such determinations.

(c) GAO REPORT ON FLEXIBILITY IN APPLYING HOME HEALTH CONDITIONS OF PARTICIPATION TO PATIENTS WHO ARE NOT MEDICARE BENEFICIARIES.—Not later than 6 months after the date of the enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on the implications if there were flexibility in the application of the medicare conditions of participation for home health agencies with respect to groups or types of patients who are not medicare beneficiaries. The report shall include an analysis of the potential impact of such flexible application on clinical operations and the recipients of such services and an analysis of methods for monitoring the quality of care provided to such recipients.

(d) OIG REPORT ON NOTICES RELATING TO USE OF HOSPITAL LIFETIME RESERVE DAYS.—Not later than 1 year after the date of the enactment of this Act, the Inspector General of the Department of Health and Human Services shall submit a report to Congress on—

(1) the extent to which hospitals provide notice to medicare beneficiaries in accordance with applicable requirements before they use the 60 lifetime reserve days described in section 1812(a)(1) of the Social Security Act (42 U.S.C. 1395d(a)(1)); and

(2) the appropriateness and feasibility of hospitals providing a notice to such beneficiaries before they completely exhaust such lifetime reserve days.

I. SUMMARY AND BACKGROUND

A. PURPOSE AND SUMMARY

There are currently over 130,000 pages of regulations for the Medicare program. These regulations are often confusing, overly burdensome and can take away from providers' time with patients. They are also needed to assure payment for services rendered and to monitor compliance with the conditions of participation and other quality of care requirements.

The purpose of H.R. 810 is to streamline paperwork requirements under the Medicare program and communicate clearer instructions to providers of services and suppliers so that they may spend more time caring for patients. At the same time, the bill does not prevent or impede the ability of the existing legal authorities to combat waste, fraud and abuse. It is also intended to reform the Medicare contracting process to make it more open by requiring competition.

B. BACKGROUND AND NEED FOR LEGISLATION

Regulatory Reform.—This bill would provide protections for beneficiaries and providers by requiring new matter introduced in a

final rule that is not a logical outgrowth of previously published material to be treated as a proposed regulation until there is public comment. It also prohibits retroactive application of regulations and policies. Finally, providers that rely on written, but erroneous guidance from the Secretary or its contractors shall not be subject to sanctions if they reasonably relied on such guidance.

Contracting Reform.—This bill would reform Medicare's contracting system for administrative functions by consolidating contracting functions for Part A and Part B, requiring competition among contractors, and providing for more flexibility for contractors.

Education and Outreach.—This bill would improve beneficiary and provider education and outreach by: requiring coordination of educational activities: providing incentives to improve contractor performance, requiring written responses within 45 days; providing a toll-free telephone number for questions about the program and outreach programs for beneficiaries and small providers. It also establishes ombudsmen for beneficiaries and providers and a demonstration program to place Medicare staff in selected Social Security offices.

Appeals.—This bill would transfer responsibility for Medicare appeals from Social Security to the Department of Health and Human Services. The Administrative Law Judges would maintain their independence from the Centers for Medicare and Medicaid Services. It also establishes requirements for independence of the Qualified Independent Contractors by ensuring no conflicts of interest. Finally, beneficiaries would be provided with more information on the disposition of their cases.

Overpayment.—This bill establishes standards for prepayment review, audits and consent settlements; allows for hardship in the case of repayment of overpayments; and limits recoupments by the program until the first independent level of appeal—qualified independent contractors—is determined. It also allows for beneficiaries and physicians to ask for prior authorization for physician office services.

Miscellaneous and Technical Provisions.—This bill contains a number of provisions that would facilitate the introduction of new technology into the system. It also limits some information requests to providers or otherwise requires the Secretary to provide the information. It provides flexibility to hospice organizations in extraordinary circumstances.

C. Legislative History

SUBCOMMITTEE ACTION

During the 107th Congress, the Subcommittee held two hearings on regulatory and contracting reform: March 15, 2001 and September 25th, 2001. After Subcommittee Chairman Johnson and Representative Stark introduced the "Medicare Regulatory Contracting Reform Act of 2001" (HR 2768) on August 2, the Committee favorably reported that bill October 4, 2001 on a voice vote. After conferring with the Energy and Commerce Committee, a revised version (HR 3391) was introduced and passed the House 408–0 on December 4, 2001. Most of the provisions in this bill were in-

corporated into the Medicare Modernization and Prescription Drug Act (HR 4954), which passed the House in June, 2002.

Action commenced on regulatory and contracting reform in the 108th Congress with the introduction of the Medicare Regulatory and Contracting Reform Act (HR 810) of 2003 by Chairman Johnson and Representative Stark on February 12. This bill is nearly identical to HR 3391 that passed the House in the 107th Congress. The Subcommittee on Health held a hearing on HR 810 on February 13th 2003, and heard testimony from CMS Administrator Tom Scully, Dr. Douglas Wood, Chairman of the Secretary's Advisory Committee on Regulatory Reform, and provider and beneficiary representatives.

On March 19, 2003, the Subcommittee on Health favorably reported on a voice vote to the full Committee H.R. 810 the "Medicare Regulatory and Contracting Reform Act of 2003." The major changes made in the Chairman's amendment in the nature of a substitute were to conform the liability for contractors to language negotiated by the Department of Justice, Office of Inspector General, CMS and contractors, and to delete obsolete provisions, which CMS is already undertaking administratively.

FULL COMMITTEE ACTION

On April 2, 2003, the Committee reported 19–13 on H.R. 810 the "Medicare Regulatory and Contracting Reform Act of 2003." The major changes made in the Chairman's amendment in the nature of a substitute were: adding a process to facilitate the adoption of updated diagnoses and procedure codes called ICD–10; allowing certain staffing companies to enroll in Medicare; and for specialized Medicare+Choice plans to exclusively serve special needs beneficiaries.

Two additional amendments were approved by the Committee. The first was to suspend the collection of unused home health data on privately-insured patients until CMS analyses how this data can be used and moves through the regulatory and public comment process. The second amendment would provide for an exception process where the Secretary can, under certain limited conditions, reinstate the nurse aide training programs of a skilled nursing facility. The Secretary (in conjunction with the State survey agencies and allowing for public notice from patients and their families and patient advocacy groups) must certify that the homes are fully in compliance with any Federal or State regulations on quality of care.

II. EXPLANATION OF THE BILL

Section 1. Short Title; Amendments to Social Security Act; Table of Contents

Current Law. No provision.

Explanation of Provision. Except as otherwise specified, the provisions would amend or repeal a section or other provisions of the Social Security Act.

Effective Date. Upon enactment.

Section 2. Findings and Construction

Current Law. No provision.

Explanation of Provision. Congress finds that the overwhelming numbers of providers are law-abiding and directs the Secretary to streamline Medicare's paperwork requirements so that time spent on patient care can increase.

None of the provisions shall be construed to (1) compromise or affect the existing legal authorities, procedures or remedies for addressing Medicare fraud or abuse whether it be criminal investigation and prosecution, civil enforcement, or administrative remedies, including those established by the False Claims Act or (2) prevent any existing legal authorities from eliminating waste, fraud, and abuse in Medicare. Also, consolidation of Medicare's administrative contracting functions (as provided for in this bill) would not consolidate the Federal Hospital Insurance Trust Fund, which pays for Part A services and the Federal Supplementary Medical Insurance Trust fund, which pays for Part B services. The bill notes that this administrative consolidation of contracting functions does not reflect any position on that issue.

Effective Date. Upon enactment.

Reason for Change. The Committee is committed to extending needed regulatory relief to providers and suppliers while at the same time protecting taxpayers from waste, fraud and abuse.

Section 3. Definitions

Current Law. No provision.

Explanation of Provision. The term, "supplier," means a physician, practitioner, facility or other nonprovider entity that furnishes Medicare items or services unless otherwise indicated. BIPA means the Medicare Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 and Secretary means the Secretary of Health and Human Services (HHS).

Effective Date. Upon enactment.

A. TITLE I—REGULATORY REFORM

Section 101. Issuance of Regulations

(a) Limitation on New Matter in Final Regulations

Current Law. No provision.

Explanation of Provision. A provision in a final regulation that is not a logical outgrowth of a previously published notice or proposed rulemaking or interim final rule would be treated as a proposed regulation and would not take effect without a separate public comment period followed by its publication as a final regulation.

Effective Date. Final regulations published on or after enactment.

Reason for Change. The provision ensures that interested parties will be given an opportunity to comment on issues addressed in regulations before they take effect. The Committee recognizes that proposed regulations for annual payment updates for providers and suppliers include proposed overall payment updates, and that specific payment amounts for specific codes or specific payment areas are not typically included until final rules. The Committee does not intend to change the requirements or application of the Administrative Procedures Act. It is the Committee's intent that if the Secretary publishes a final rulemaking document which includes a provision that is not a logical outgrowth of a previously published notice of proposed rulemaking, such provision will not take effect

until there is further opportunity for public comment and a publication of the provision again as a final regulation.

Section 102. Compliance With Changes in Regulations and Policies

(a) No Retroactive Application of Substantive Changes

Current Law. No provision.

Explanation of Provision. A substantive change in a regulatory or a subregulatory issuance would not be applied retroactively to items or services, unless the Secretary determines that retroactive application (1) would be necessary to comply with statutory requirements; or (2) would be beneficial to the public interest.

Effective Date. For substantive changes issued on or after enactment.

Reason for Change. This provision will ensure that Medicare's rules are not generally applied retroactively.

(b) Timeline for Compliance With Substantive Changes After Notice

Current Law. No provision.

Explanation of Provision. A substantive change would not become effective before 30 days after the date the change is issued or published. The Secretary would be able to waive the 30–day period to comply with statutory requirements or if such waiver is in the public interest. If an earlier date is established, the Secretary would be required to include a brief explanation of such finding in the issuance or publication of the substantive change. No compliance action would be permitted against a provider or supplier for goods and services furnished before the effective date of the substantive change.

Effective Date. For compliance actions undertaken on or after enactment.

Reason for Change. This provision will ensure providers and suppliers have sufficient time to make any changes to systems needed to comply with changes in regulations.

(c) Reliance on Guidance

Current Law. No provision.

Explanation of Provision. A provider or supplier who reasonably relied on erroneous guidance would not be subject to any sanction or penalties, including repayment, provided the following conditions were met: (1) The provider or supplier follows written guidance (which may be transmitted electronically) provided by the Secretary or a Medicare contractor when furnishing an item or service and submitting a claim; (2) the Secretary finds that the circumstances relating to the furnished items and services have been accurately presented in writing to the contractor; and (3) the guidance is inaccurate. This provision would not prevent recoupment or repayment (without additional penalty) if the overpayment were solely the result of a clerical or technical operational error.

Effective Date. Upon enactment, but would not apply to sanctions where notice was provided on or before enactment.

Reason for Change. This provision will ensure that providers and suppliers who, in good faith based on the information received from contractors will not be vulnerable to recovery if it turns out that

the contractor was in error. Providers should be able to rely on the directions or guidance provided by their Medicare contractors.

Section 103. Reports and Studies Relating to Regulatory Reform

Current Law. No provision.

Explanation of Provision. The legislation has two studies in this area. First, the Comptroller General of the United States (GAO) would be required to conduct a study to determine the appropriateness and feasibility of providing the authority to the Secretary to issue legally binding advisory opinions on the interpretation and application of Medicare regulations. The study would examine the appropriate time frame for issuing the decisions as well as the need for additional staff and funding. GAO would submit the study not later than one year after enactment.

Second, the Secretary would be required to report to Congress on the administration of the Medicare program and inconsistencies among existing Medicare statutory or regulatory provisions. The report would include (1) information from beneficiaries, providers, suppliers, Medicare Beneficiary and Provider Ombudsmen (established in Section 303 of this legislation), and Medicare contractors; (2) descriptions of efforts to reduce inconsistencies; and (3) recommendations from the Secretary for appropriate legislation or administrative actions. The report would be due no later than two years after enactment and every two years thereafter.

Effective Date. Upon enactment.

Reason for Change. The Committee is interested in receiving additional information regarding both advisory opinions and inconsistencies in Medicare regulations.

B. TITLE II—CONTRACTING REFORM

Section 201. Increased Flexibility in Medicare Administration

(a) Consolidation and Flexibility in Medicare Administration

Current Law. Section 1816 of the Social Security Act authorizes the Secretary to establish agreements with fiscal intermediaries nominated by different provider associations to make Medicare payments for health care services furnished by institutional providers. Section 1842 of the Act authorizes the Secretary to enter into contracts with health insurers (or carriers) to make Medicare payments to physicians, practitioners and other health care suppliers. Section 1834(a)(12) of the Act authorizes separate regional carriers for the payment of durable medical equipment (DME) claims. Section 1893 authorizes the Secretary to contract for certain program safeguard activities under the Medicare Integrity Program (MIP).

Certain terms and conditions of the contracting agreements for fiscal intermediaries and carriers are specified in the Medicare statute. Medicare regulations coupled with long-standing agency practices have further limited the way that contracts for claims administration services can be established. Specifically, the contracts are awarded without full and open competition; generally must cover the range of claims processing and related activities; cannot be terminated without cause and without the opportunity for a public hearing; and incorporate cost-based, not performance-based, reimbursement methods with no incentive bonuses.

Certain functions and responsibilities of the fiscal intermediaries and carriers are specified in the statute as well. The Secretary may not require that carriers or intermediaries match data obtained in its other activities with Medicare data in order to identify beneficiaries who have other insurance coverage as part of the Medicare Secondary Payer (MSP) program. With the exception of prior authorization of DME claims, an entity may not perform activities (or receive related payments) under a claims processing contract to the extent that the activities are carried out pursuant to a MIP contract. Performance standards with respect to the timeliness of reviews, fair hearings, reconsiderations and exemption decisions are established as well.

A Medicare contract with an intermediary or carrier may require any of its employees certifying or making payments provide a surety bond to the United States in an amount established by the Secretary. Neither the contractor nor the contractor's employee who certifies the amount of Medicare payments is liable for erroneous payments in the absence of gross negligence or intent to defraud the United States. Neither the contractor nor the contractor's employee who disburses payments is liable for erroneous payments in the absence of gross negligence or intent to defraud the United States, if such payments are based upon a voucher signed by the certifying employee.

Explanation of Provision. The legislation would add Section 1874A to the Social Security Act to permit the Secretary to enter into contracts with any entity to serve as a Medicare administrative contractor. These contractors would perform or secure the performance (through subcontracting) of some or all of the following tasks: determine payment amounts; make payments; educate and assist beneficiaries; provide consultative services; communicate with providers and suppliers; educate and offer technical assistance to providers; and perform additional functions as necessary. An entity eligible to enter into a contract with respect to the performance of a particular function as an entity would (1) have demonstrated capability to carry out such function; (2) comply with conflict of interest standards that are generally applicable under Federal acquisition and procurement; (3) have sufficient assets to financially support the performance of such functions and (4) meet other requirements imposed by the Secretary. The claims processing jurisdiction of Medicare administrative contractor would be determined by the scope of the contract awarded to the entity. Specifically, the Medicare administrative contractor that would perform a particular function is the entity that has the contract to perform that function for any given beneficiary, any given provider or supplier, or class of same.

The Federal Acquisition Rules (FAR) would apply to Medicare administrative contracts except to the extent they are inconsistent with a specific Medicare requirement. The Secretary would be required to use competitive procedures when entering into a Medicare administrative contract and would take into account performance quality, price, and other factors. The Secretary would be able to renew a contract for up to five years without regard to statutory requirements concerning competitive contracting if the entity has met or exceeded specified performance standards. The Secretary would be able to transfer functions among contractors consistent

with these provisions. The Secretary would be required to (1) ensure that performance quality is considered in such transfers and (2) provide notice of such transfer (in the Federal Register or otherwise) including a description of the transferred functions, the affected providers and suppliers, and includes contractor contact information.

The Secretary would be required to (1) provide incentives for the Medicare administrative contractors to provide efficient, high-quality services; and (2) develop performance standards with respect to each of the payment, provider service, and beneficiary service functions required of the contractors. In developing the performance standards, the Secretary would be able to consult with providers and suppliers, organizations representing Medicare beneficiaries, and Medicare contractors. In developing the performance requirements for Medicare administrative contractors, the Secretary may include satisfaction of beneficiaries as a standard for measuring performance. The Secretary would be required to contract only with those entities that will (1) perform efficiently and effectively; (2) meet standards for financial responsibility, legal authority and service quality among other pertinent matters; (3) agree to furnish timely and necessary data; and (4) maintain and provide access to necessary records and data.

The performance requirements would be (1) set forth in the contract between the Secretary and the appropriate Medicare contractor; (2) used to evaluate contractor performance; and (3) consistent with the contract's written statement of work. The statement of work and contract are public documents. A Medicare administrative contract would contain provisions deemed necessary by the Secretary and may provide for advances of Medicare funds for the purposes of making payments to providers and suppliers. In developing contract performance requirements for Medicare administrative contractors, the Secretary would be required to consider the inclusion of the existing standards in effect for timeliness of reviews, reconsiderations and exemption decisions.

The existing MSP provision would apply: the Secretary would not be able to require contractors to match their data with Medicare data for the purposes of the identifying beneficiaries with other insurance coverage. The Secretary would assure that the activities of the Medicare administrative contractors do not duplicate the Medicare Integrity Program (MIP) functions except with respect to the prior authorization of durable medical equipment. An entity with a MIP contract would not be treated as a Medicare administrative contractor simply because it has a MIP contract.

A Medicare administrative contractor and any of its employees certifying or disbursing payments may be required to provide a surety bond to the United States in an amount established by the Secretary. It is the intent of Congress that the definition of a surety bond in this instance includes fidelity bonds and the Secretary has the authority to request fidelity bonds.

A Medicare administrative contractor, certifying officer, or disbursing officer shall not be liable for erroneous payments in the absence of reckless disregard or intent to defraud the United States. While Medicare administrative contractors are not liable for inadvertent billing errors, as in the past, they are liable for all penalties and damages resulting from reckless disregard of their obli-

gations under their Medicare administrative contracts or intent to defraud the United States. The "reckless disregard" standard is the same as that under the False Claims Act which has been used effectively by whistleblowers and the Department of Justice to uncover and penalize fraud against the Medicare program by some fiscal intermediaries and carriers. This "reckless disregard" standard, which does not require proof of specific intent to defraud, is designed to balance the practical need to shelter Medicare Administrative Contractors from frivolous civil litigation by disgruntled providers or beneficiaries with the Medicare program's interest in protecting itself from contractor fraud. This section makes it clear that the False Claims Act continues, as in the past, to remain available as a remedy for fraud against Medicare by contractors, and that, as in the past, the damages and penalties which the Medicare program is entitled to recover from fraudulent contractors include not just administrative payments but also the affected payments from the Medicare trust funds.

The Secretary would be able to indemnify a Medicare administrative contractor, subcontractor, or employee who is made a party to any judicial or administrative proceeding arising from the claims administration process to an appropriate extent as determined by the Secretary and specified in the contract. Indemnification in this case may include payment of judgments, certain settlements, awards and costs (including reasonable legal expenses). Settlement proposals would not be negotiated or compromised without prior written approval by the Secretary. The Secretary would not be able to provide any indemnification if the liability arises directly from conduct that is determined in the proceeding or by the Secretary to be criminal in nature or fraudulent. If indemnification is provided before such determination is made that such costs arose directly from such conduct, the contractor would reimburse the Secretary for these costs. The provisions would not change common law immunity available to the Medicare contractor or other party, or permit the payment of costs not otherwise allowable, reasonable or allocable under the Federal Acquisition Regulation.

Effective Date. See subsection (d).

Reason for Change. Medicare's current contracting represents an antiquated, inefficient, and closed system based on cozy relationships between the government, contractors and providers.

Medicare contracting is antiquated because contractors may not provide service for the entire Medicare program, or particular functions within the program; rather Fiscal Intermediaries administer claims for facilities and carriers administer claims for all other providers. It has failed to keep pace with integrated claims administration practices in the private sector.

Medicare contracting is inefficient because Medicare does not award contracts for Fiscal Intermediaries through competitive procedures, but rather on provider nomination.

Medicare contracting is a closed system. All but one of the contractors today have been with Medicare since the program's inception 38 years ago, and only insurers can provide contracting services under current law.

This provision permits greater flexibility in contracting for administrative services between the Secretary and the Medicare contractors (entities that process claims under Part A and Part B of

the Medicare program), including the flexibility to separately contract for all or parts of the contractor functions. The Secretary also may contract with a wider range of entities, so that the most efficient and effective contractor can be selected.

These amendments require the Secretary to contract competitively at least once every five years for the administration of benefits under Parts A and B. In conjunction with the elimination of cost contracts, it is intended to create incentives for improved service to beneficiaries and to providers of services and suppliers.

(b) Conforming Amendments to Section 1816 (Relating to Fiscal Intermediaries)

Current Law. Section 1816 of the Social Security Act establishes the provider nomination process, the contracting specifications, and performance standards for fiscal intermediaries that currently contract with Medicare to process claims and perform other related administrative activities for institutional providers.

Explanation of Provision. The provisions establish that the activities of fiscal intermediaries in administering Medicare would be conducted through contracts with Medicare administrative contractors as set forth in subsection (a). The provider nomination process and contracting specifications would be repealed. Certain performance standards with respect to the processing of clean claims would be retained. Certain annual reporting requirements concerning the contractor's overpayment recovery efforts would be retained.

Effective Date. See subsection (d).

Reason for Change. These amendments provide a basis for a unified contracting system for the administration of Parts A and B, identical to the recent Congressionally mandated structure of the Medicare Integrity Program contractors. Consolidation of contracting duties as set forth in this legislation does not constitute consolidation of the Hospital Insurance and Medical Supplementary Insurance Trust Funds, or reflect any position on that issue. In addition, the elimination of provider nomination, which hospitals have rarely been allowed to exercise in recent years, is essential for bringing full and open competition into the contracting functions of the Medicare program.

(c) Conforming Amendments to Section 1842 (Relating to Carriers)

Current Law. Section 1842 of the Social Security Act establishes that carriers will be used to administer certain Medicare benefits as well as the contracting requirements and certain performance standards for those activities.

Explanation of Provision. The provisions would establish that the activities of carriers administering Medicare would be conducted through contracts with Medicare administrative contractors as set forth in subsection (a). Certain instructions including those pertaining to nursing facilities payments, claims assignment, physician participation, overpayment recoveries and billing by suppliers would be retained. Certain performance standards with respect to the processing of clean claims would be retained. Contracting specifications and other conforming changes would be established. The Secretary, not the contractor, would be responsible for taking necessary actions to assure that reasonable payments are made, for those made on both a cost and charge basis. The Secretary, not the

contractor, would be responsible for maintaining a toll-free telephone number for beneficiaries to obtain information on participating suppliers. Since the Carrier fair hearing requirement were eliminated in BIPA, the requirements for the hearing are eliminated to conform with existing law. Certain annual reporting requirements concerning the contractor's overpayment recovery efforts would be retained.

The Committee directs the Secretary's attention to the provision of the Balanced Budget Act of 1997 requiring CMS to designate no more than five regional carriers to process laboratory claims. This provision was passed in order to streamline the processing of laboratory claims and was to be implemented by July 1, 1999, but CMS has taken no action to date. In consultation with the clinical laboratory industry, CMS may consider other potential solutions, including the designation of a single contractor to process all claims of laboratory entities operating in more than one state. CMS is directed to report back to the Committee on Ways and Means and the Committee on Energy and Commerce within three months detailing the action it has taken to implement this directive.

Effective Date. See subsection (d).

Reason for Change. The provision establishes a basis for a unified contracting system, identical to the structure implemented for the Medicare Integrity Program (MIP) contractors. It is important to note, however, that consolidation of contracting duties as set forth in this legislation does not constitute consolidation of the Hospital Insurance and Medical Supplementary Insurance Trust Funds, or reflect any position on that issue. In addition, the Secretary would have the flexibility to choose the best contractor(s) to provide telephone information on suppliers which is intended to reduce administrative costs and improve quality. Since the carrier fair hearing requirement was eliminated in previous legislation, the requirements for the hearing are eliminated in order to conform with existing law.

(d) Effective Date; Transition Rule

Current Law. No provision.

Explanation of Provision. Except as otherwise provided in this subsection, the provisions in this section would be effective October 1, 2005. The Secretary would be authorized to take necessary actions prior to that date in order to implement these amendments on a timely basis to transition from the contracts established under sections 1816 and 1842 of the Social Security Act to those established under the new section 1874A created by this legislation. The transition would be consistent with the requirement that the administrative contracts be competitively bid by October 1, 2010. The requirement that MIP contracts be awarded on a competitive basis would continue to apply and would not be affected by the provisions in this section. The MIP contracting exception that allows agreements according to current law would be deemed to be a contract established under the new authority of 1874A and would continue existing activities. The Secretary has the authority to recognize the appropriate termination costs of the current contractors during the transition from cost contracts to competitively bid contracts.

(e) References

Current Law. No provision.

Explanation of Provision. After this section becomes effective, any reference to fiscal intermediary or carrier would be considered a reference to the appropriate Medicare administrative contractor.

(f) Reports on Implementation

Current Law. No provision.

Explanation of Provision. The Secretary would submit an implementation plan to Congress and GAO no later than October 1, 2004. GAO would evaluate the plan and include appropriate recommendations no later than six months after the plan is received. No later than October 1, 2008, the Secretary would be required to submit a status report to Congress including (1) the number of contracts that have been competitively bid; (2) the distribution of functions among contracts and contractors; (3) a timeline for complete transition to full competition; and (4) a detailed description of changes to contractor oversight and management.

Effective Dates. Upon enactment.

Section 202. Requirements for Information Security

Current Law. No provision.

Explanation of Provision. Medicare administrative contractors that determine and make payments would be required to implement a contractor-wide information security program that meets the requirements imposed on Federal agencies to ensure the security, integrity, confidentiality, authenticity, and availability of operational data and systems supporting operations. An annual audit of the information security at each Medicare administrative contractor: (1) would be performed by an independent entity that meets the independence requirements specified by the Office of the Inspector General (OIG) in HHS; and (2) would test the effectiveness of the information security techniques for an appropriate subset of the contractor's systems. An audit of new contractors (those that have not been fiscal intermediaries or carriers) would be required prior to the start of their performing Medicare payment functions. An audit of existing contractors (those that are now fiscal intermediaries and carriers) would be required to be completed within one year from enactment. The results of the audits would be reported promptly to the OIG which will submit a report annually to Congress. These provisions would be equally applicable to fiscal intermediaries and carriers as to Medicare administrative contractors.

Effective Date. Upon enactment.

Reason for Change. The increased reliance by the Federal government on the Internet and related telecommunications technologies has resulted in enhanced inter-connectivity and interdependencies associated with Federal computer systems and between federal and private computer systems. Over the past several years, this inter-connectivity or "networking" has resulted in increased security vulnerabilities that have put at greater risk computer systems and data that are critical to ensuring national and economic security and public health and welfare, including sensitive, non-public information that is collected and maintained by CMS and its business partners.

Investigations have revealed significant security weaknesses, which the agency has been working to address. Some of the computer security concerns identified include weak password management, inadequate access controls, excessive user privileges, improper network configurations, and inadequate testing of critical systems. In addition, the OIG conducted assessments of financial controls—including electronic data processing controls—at CMS and its major Medicare contractors, and, in every year since 1997, the OIG has identified computer security controls to be a material weakness at both CMS and the Medicare contractors reviewed.

Section 202 is intended to assist CMS in identifying and working with contractors to address potential security deficiencies in order to ensure that sensitive, non-public information related to the processing of Medicare claims is adequately secure from unauthorized access, misuse, or destruction.

C. TITLE III—EDUCATION AND OUTREACH IMPROVEMENTS

Section 301. Provider Education and Technical Assistance

(a) Coordination of Education Funding

Current Law. Medicare's provider education activities are funded through the program management appropriation and through the Education and Training component of the Medicare Integrity Program (MIP). Both claims processing contractors (fiscal intermediaries and carriers) and MIP contractors may undertake provider education activities.

Explanation of Provision. The provision would add Section 1889 to the Social Security Act which would require the Secretary to (1) coordinate the educational activities provided through the Medicare administrative and MIP contractors and (2) to submit an evaluation to Congress, no later than October 1, 2002, on actions taken to coordinate the funding of provider education.

Effective Date. Upon enactment.

Reason for Change. This provision is intended to ensure that federal spending on provider education is coordinated and used as efficiently as possible to maximize the value obtained from the investment. It is not intended to change the proportion of Medicare Integrity Program funds spent on provider education.

(b) Incentives to Improve Contractor Performance

Current Law. No specific statutory provision. Since FY1996, as part of the audit required by the Chief Financial Officers Act, an estimate of improper payments in Medicare fee-for-service has been established annually. As a recent initiative, CMS is implementing a comprehensive error rate testing program to produce national, contractor specific, benefit category specific and provider specific paid claim error rates.

Explanation of Provision. The Secretary would be required to use the specific claims payment error rates or similar methodology at each Medicare administrative contractor to provide incentives for such contractors to effectively educate providers on proper claims procedures. This methodology would apply to existing fiscal intermediaries and carriers in the same manner as it applies to Medicare administrative contractors. No later than October 1, 2004, GAO would submit to Congress and to the Secretary a report on

the adequacy of the methodology, including recommendations as appropriate. No later than October 1, 2004, the Secretary would be required to report to Congress on (1) the use of the claims error rate methodology in assessing the effectiveness of contractors' provider education and outreach programs and (2) whether methodology should be used as a basis to pay contractors' performance bonuses.

Effective Date. As specified.

Reason for Change. This provision would ensure that the Department monitors contractor performance for claims payment error rates, and it would identify best practices for provider education—all with the goal of reducing payment errors and helping providers and suppliers better comply with program requirements. It is the Committee's intent that, in consultation with representatives of providers and suppliers, the Secretary shall identify and encourage best practices developed by contractors for educating providers and suppliers.

(c) Provision of Access to and Prompt Responses From Medicare Administrative Contractors

Current Law. No specific statutory provision. Statutory provisions generally instruct carriers to assist providers and others who furnish services in developing procedures relating to utilization practices and to serve as a channel of communication relating information on program administration. Fiscal intermediaries are generally instructed to (1) provide consultative services to institutions and other agencies to enable them to establish and maintain fiscal records necessary for program participation and payment and (2) serve as a center for any information as well as a channel for communication with providers.

Explanation of Provision. The Secretary would be required to develop a communication strategy with beneficiaries, providers and suppliers. Each Medicare administrative contractor would be required to (1) provide general written responses (which may be through electronic transmission) in a clear, concise and accurate manner to written inquiries from beneficiaries, providers and suppliers within 45 business days; (2) provide a toll-free telephone number where these interested parties may obtain billing, coding, claims, coverage and other appropriate Medicare information; (3) maintain a system for identifying which employee provided both the written and oral information; and (4) monitor the accuracy, consistency, and timeliness of the information provided. The Secretary would be required to establish and make public the standards used to monitor the accuracy, consistency, and timeliness of information provided in response to written and telephone inquiries. The standards would be developed in consultation with provider, supplier, and beneficiary organizations and would be consistent with the contractors' performance requirements. The Secretary would be able to directly monitor the quality of the information so provided. These provisions would also apply to existing fiscal intermediaries and carriers. The Medicare administrative contractor is required to record the subject matter and content of any advice, in part, to facilitate tracking the accuracy of the advice.

Effective Date. By October 1, 2004.

Reason for Change. This provision is intended to improve contractor accountability to make contractors more responsive to providers and suppliers, and to increase the accuracy, timeliness and reliability of the information provided in response to the questions received.

(d) Improved Provider Education and Training

Current Law. In FY2000, $54.8 million was spent on provider education and training activities: about $43 million came from the program management appropriation and about $12 million came from the Provider Education and Training component of MIP. In FY2001, about $57.3 million was budgeted for these activities.

Explanation of Provision. The provisions would authorize $25 million in Medicare appropriations in FY2005 and FY2006 and such funds as necessary in subsequent years to increase provider education and training and to improve the accuracy and quality of contractor responses. The Committee intends for this amount to be provided in addition to current funding levels. Starting on October 1, 2004, the contractors' training activities would accommodate the special needs of small providers and suppliers. The provisions define a small provider as an institution with fewer than 25 full-time equivalents (FTEs) and a non-facility based provider or supplier with fewer than 10 FTEs.

Effective Date. Upon enactment and as specified.

Reason for Change. This provision acknowledges that contractors are being instructed to significantly improve their provider education and training efforts, and accordingly authorizes new funds to be available for those purposes.

(e) Requirement To Maintain Internet Sites

Current Law. No provision.

Explanation of Provision. The Secretary and each contractor would be required to maintain an Internet site that provides answers to frequently asked questions in an easily accessible format as well as other materials published by the contractor.

Effective Date. By October 1, 2004.

Reason for Change. This provision will facilitate greater ease of provider and supplier access to information provided by Medicare's contractors.

(f) Additional Provider Education Provisions

Current Law. No provision.

Explanation of Provision. A Medicare contractor would not be able to use attendance records at educational programs or information gathered during these programs to select or track candidates for audit or prepayment review. Nothing in the proposed legislation would require Medicare administrative contractors to disclose information that would compromise pending law enforcement activities or reveal findings of law enforcement-related audits.

Effective Date. Upon enactment.

Reason for Change. This provision addresses a concern raised by providers and suppliers that their participation in educational forums has been used to trigger audits. Participation in educational forums should be encouraged not discouraged.

Nothing in this section or section 1893(g) shall be construed as preventing the disclosure by a Medicare contractor of information on attendance at education activities for law enforcement purposes. Nothing in this section or section 1893(g) shall be construed as providing for the disclosure by a Medicare contractor of the claims processing screens or computer edits used for identifying claims that will be subject to review.

Section 302. Small Provider Technical Assistance Demonstration Program

Current Law. No provision.

Explanation of Provision. The Secretary would be required to establish a demonstration program and contract with qualified entities to offer technical assistance, when requested and on a voluntary basis, to small providers or suppliers. Small providers and suppliers would be those institutional providers with less than 25 full-time equivalents (FTEs) or suppliers with less than 10 FTEs. Technical assistance would include direct, in-person examination of billing systems and internal controls by qualified entities such as peer review organizations or other entities. In awarding these contracts, the Secretary would be required to consider any prior investigations of the entity's work by the Office of the Inspector General (OIG) in HHS or the GAO. Participating providers and suppliers would be required to pay an amount estimated and disclosed in advance that would equal 25 percent of the cost of the technical assistance they received. Absent indications of fraud, errors found in the review would not be subject to recovery if the problem is corrected within 30 days of the on-site visit and remains corrected for an appropriate period. However, this protection would only apply to claims filed as part of the demonstration project, would last only for the duration of the project and only as long as the provider or supplier was participating in the project. GAO, in consultation with the OIG, would be required to evaluate and provide recommendations on the continuation of the demonstration project no later than two years after its implementation. The evaluation would include a determination of whether claims error rates were reduced for providers and suppliers who participated in the program. The provision would authorize $1 million in FY2005 and $6 million in FY2006 of appropriations from the Medicare Trust Funds to carry out demonstration project.

Effective Date. Upon enactment.

Reason for Change. Many large providers and suppliers have contracts with private consulting firms to help them navigate their interactions with the Medicare program. This type of assistance can be prohibitively expensive for small providers and suppliers—but they are also required to comply with complex program rules and regulations. This provision creates a new demonstration program to facilitate small provider and supplier access to expert technical assistance. The demonstration will also test whether encouraging technical assistance on the front end to help providers and suppliers play by the rules can save the program money in the long term by promoting greater program compliance.

Section 303. Medicare Provider Ombudsman; Medicare Beneficiary Ombudsman

(a) Medicare Provider Ombudsman

Current Law. No provision.

Explanation of Provision. The Secretary would be required to appoint a Medicare Provider Ombudsman within HHS to (1) to resolve unclear guidance and provide confidential assistance to providers and suppliers regarding complaints or questions about the Medicare program including peer review and administrative requirements; and (2) recommend changes to improve program administration. The Ombudsman would not advocate any increases in payments or expanded coverage, but would identify issues and problems in current payment and coverage policies.

Effective Date. One year after enactment.

Reason for Change. Providers are currently confronted with a morass of bureaucracy and regulation, with no clear individual to assist them. The new ombudsman will help providers navigate Medicare's complicated rules and regulations.

The Medicare Provider Ombudsman shall make recommendations to the Secretary concerning how to respond to recurring patterns of confusion in the Medicare program. Such a recommendation may include calling for the suspension of the imposition of provider sanctions (except those sanctions relating to the quality of care) where there is widespread confusion in program administration. Nothing in this section shall be construed as allowing for the suspension of provider sanctions relating to the quality of care, regardless of whether widespread confusion in the Medicare program exists.

(b) Medicare Beneficiary Ombudsman

Current Law. No provision.

Explanation of Provision. The Secretary would be required to appoint a Medicare Beneficiary Ombudsman within HHS from individuals with health care expertise, advocacy, and education of Medicare beneficiaries. The ombudsman would (1) receive complaints, grievances, and requests for information from Medicare beneficiaries; (2) provide assistance with respect to those complaints, grievances and requests, including assistance to beneficiaries who appeal claims determinations or those affected by the decisions of Medicare+Choice organizations to leave Medicare; and (3) submit an annual report to Congress and the Secretary describing activities and recommending changes to improve program administration. The Ombudsman would not advocate any increases in payments or expanded coverage, but would identify issues and problems in current payment and coverage policies.

To the extent possible, the Beneficiary Ombudsman would work with the Health Insurance and Assistance Counseling Programs authorized under Section 4360 of OBRA 1990, to facilitate the provision of information to Medicare beneficiaries regarding Medicare+Choice plans and any changes related to those plans. In addition, nothing in this section would preclude further collaboration, as appropriate, between the Beneficiary Ombudsman and these programs.

Effective Date. One year after enactment.

Reason for Change. Beneficiaries confront a morass of bureaucracy and regulation, with no clear individual to assist them. This new ombudsman will help beneficiaries navigate Medicare's complicated rules and regulations.

(c) Funding

Current Law. No provision

Explanation of Provision. The provision would authorize appropriations of necessary sums in FY2004 and subsequently from the appropriate Medicare Trust Funds for the Ombudsman programs.

Effective Date. Upon enactment.

Reason for Change. The Committee acknowledges that implementing these new functions will have a cost and accordingly authorize necessary appropriations.

(d) Use of Central Toll Free Number (1–800–MEDICARE)

Current Law. The Secretary is required to prepare and distribute an annual notice explaining Medicare benefits and limitations to coverage to Medicare beneficiaries. The Secretary is also required to provide information via a toll-free telephone number.

Explanation of Provision. The Secretary would be required to establish a toll-free number (1–800–MEDICARE) which will transfer individuals with questions or seeking help to the appropriate entities. The transfer would occur with no charge. This toll-free number would be the general information and assistance number listed on the annual notice provided to beneficiaries. GAO would be required to (1) monitor the adequacy, accuracy, and consistency of the information provided to Medicare beneficiaries through the toll-free 1–800–MEDICARE number and (2) examine the education and training of those providing the information through the toll-free number. GAO would be required to submit a report to Congress no later than one year from enactment. This toll-free number is intended to supplement, not replace, information and assistance available through non-federal sources. For example, contact information for the State Health Insurance Assistance Programs (SHIPs) should still be listed in the beneficiary handbook.

Effective Date. Upon enactment.

Reason for Change. The beneficiary handbook currently provides many pages of phone numbers, which can be very confusing for beneficiaries, rather than a single number that then can triage and transfer beneficiaries to the appropriate person or entity. This provision will promote better access to information for beneficiaries.

Section 304. Beneficiary Outreach Demonstration Program

Current Law. No provision.

Explanation of Provision. The Secretary would be required to establish a 3-year demonstration project where Medicare specialists who are HHS employees are placed in at least six SSA offices to advise and assist Medicare beneficiaries. The SSA offices would be those with a high-volume of visits by Medicare beneficiaries; at least two of which would be in rural areas. In the rural SSA offices, the Secretary would provide for the Medicare specialists to travel among local offices on a scheduled basis. The Secretary would be required to (1) evaluate the project with respect to beneficiary utilization, beneficiary satisfaction, and cost-effectiveness and (2) rec-

ommend whether the demonstration should be expanded and made permanent.

Effective Date. Upon enactment.

Reason for Change. This provision makes Medicare experts available in six Social Security Administration offices to assist beneficiaries and answer their questions. The demonstration will test whether such outsourced Medicare specialists improve beneficiary understanding of the program and beneficiary satisfaction.

Section 305. Notification About Skilled Nursing Facility Benefits

Current Law. No provision.

Explanation of Provision. The Secretary would be required to provide beneficiaries with information about the remaining number of days of skilled nursing facility coverage.

Effective Date. For notices provided during calendar quarters beginning more than six months after enactment.

Reason for Change. Beneficiaries are not always aware that their Medicare coverage is running out, and may need time to arrange alternate financing for continued skilled nursing facility care. This provision will provide beneficiaries with advance notice of the expiration of their skilled nursing benefit so that they have time to make arrangements without disruptions in care.

Section 306. Information on Medicare-Certified Skilled Nursing Facilities in Hospital Discharge Plans

Current Law. No provision.

Explanation of Provision. The Secretary would make publicly available information that enables hospital discharge planners, Medicare beneficiaries, and the public to identify skilled nursing facilities that are participating in Medicare.

Hospital discharge plans would be required to identify, for individuals who are likely to need post-hospital extended care services, the availability of Medicare-certified skilled nursing facilities that serve the area in which the patient resides.

Effective Date. Not later than 6 months after the Secretary provides for the availability of information needed for discharge plans.

Reason for Change. The Committee has received reports of beneficiaries being discharged to non-Medicare skilled nursing facilities or beds. This provision is intended to assure that beneficiaries are given information during discharge planning about Medicare participating facilities. Thus, this provision would ensure that beneficiaries who need post acute care are notified about the availability of Medicare participating skilled nursing facilities in the area.

D. Title IV—Appeals and Recovery

Section 401. Transfer of Responsibility for Medicare Appeals

Current Law. Medicare beneficiaries and, in certain circumstances, providers and suppliers of health care services may appeal claims that are denied or payments that are reduced. Section 1869 of the Social Security Act, which covers the Medicare claims appeals process, was amended by BIPA in its entirety, but the BIPA provisions are not yet effective. Generally, parties who have been denied coverage of an item or service have the right to

appeal that decision through a series of administrative appeals and then into federal district court if the amounts of disputed claims in question meet certain thresholds at each step of the appeals process. A hearing by an administrative law judge (ALJ) in the Social Security Administration (SSA) with review by the Department Appeals Board (DAB) is a component of the administrative appeals process.

Explanation of Provision. By October 1, 2004, the Commissioner of SSA and the Secretary would develop a plan to transfer the functions of the administrative law judges (ALJs) who are responsible for hearing Medicare and Medicare related cases from SSA to HHS. The plan would be transmitted to Congress and GAO no later than October 1, 2004. The GAO would evaluate the plan and submit a report to Congress within six months. The Secretary and the Commissioner of SSA would implement the transition plan and transfer the ALJ functions no earlier than July 1, 2005 and no later than October 1, 2005. The Secretary would (1) assure the ALJ's independence from the Centers of Medicare and Medicaid Services (CMS) by placing the ALJs in an administrative office that is organizationally and functionally separate from CMS; and (2) locate the ALJs with an appropriate geographic distribution to ensure access. Subject to appropriations, the Secretary would be permitted to hire ALJs and support staff with priority given to ALJs with experience in handling Medicare appeals. Amounts previously paid to SSA for the ALJs performing the ALJ functions would be payable to the Secretary for the transferred functions. The Secretary would be permitted to enter into arrangements with SSA to share office space, support staff, and other resources with appropriate reimbursement from the Medicare trust funds. Increased appropriations would be permitted to increase the number of ALJs and support staff; improve education and training for ALJs and their staff; and increase DAB staff.

Effective Date. Upon enactment.

Reason for Change. The Office of Inspector General has identified moving the functions of the Medicare Administrative Law Judges to the Department of Health and Human Services as an important priority in improving the appeals system. This provision makes that transition and increases the emphasis on providing training Administrative Law Judges and their staffs to increase their expertise in Medicare's rules and regulations. The SSA Commissioner and the Secretary are instructed to work together on the transition plans in order to assure that the transition does not adversely affect the SSA ALJ appeals system. The Committee objects to recent proposals to locate the ALJs in CMS.

The transition plan shall include information on the following:

- Workload—The number of such administrative law judges and support staff required now and in the future to hear and decide such cases in a timely manner, taking into account the current and anticipated claims volume, appeals, number of beneficiaries, and statutory changes;
- Cost Projections—Funding levels required for fiscal year 2004 and subsequent fiscal years under this subsection to hear such cases in a timely manner;
- Transition Timetable—A timetable for the transition;

- Regulations—The establishment of specific regulations to govern the appeals process;
- Case Tracking—The development of a unified case tracking system that will facilitate the maintenance and transfer of case specific data across both the fee-for-service and managed care components of the Medicare program;
- Feasibility of Precedential Authority—The feasibility of developing a process to give binding, precedential authority to decisions of the Departmental Appeals Board in the Department of Health and Human Services that address broad legal issues; and
- Access to Administrative Law Judges—The feasibility of filing appeals with administrative law judges electronically, and the feasibility of conducting hearings using tele- or videoconference technologies.

Section 402. Process for Expedited Access to Judicial Review

(a) In General

Current Law. Section 521 of BIPA (which is not yet implemented) amends Section 1869 to establish deadlines for filing appeals and for making decisions in the Medicare appeals process. Generally, an initial determination is to be completed no later than 45 days from the date a claim for benefits is received; an individual dissatisfied with an initial determination is entitled to a redetermination by a carrier or fiscal intermediary if requested within 120 days of the determination date. The redetermination is to be completed no later than 30 days from the request date. The Secretary may reopen or revise any initial determination or reconsidered determination under guidelines established by regulation.

An individual dissatisfied with the redetermination is entitled to reconsideration by a qualified independent contractor (QIC) if the request is initiated within 180 days of the notice of the adverse redetermination. With certain exceptions, a QIC reconsideration decision is to be completed within 30 days from the date a timely request has been filed. After a QIC's reconsideration, if the remaining contested amount is greater than $100, an individual is entitled to a hearing by an administrative law judge and then a review by the DAB. Both the ALJ hearing and the DAB review are to be completed within 90 days of a timely filed request for such an action.

If the dispute is not satisfactorily resolved and the contested amounts are greater than $1,000, the individual is entitled to judicial review of the decision. Under certain circumstances, a beneficiary is entitled to an expedited determination with accelerated deadlines. BIPA also provides for an expedited hearing under Section 1869, where the moving party alleges that no material issues of fact are in dispute; the Secretary makes an expedited determination as to whether any such facts are in dispute and, if not, renders a decision expeditiously.

Explanation of Provision. The Secretary would establish an appeals process for a provider, supplier, or beneficiary that permits access to judicial review when a review panel determines that no entity in the administrative appeals process has authority to decide the question of law or regulation in controversy and where material facts are not in dispute. The appellant would be able to make such

request only once with respect to a question of law or regulation for a specific dispute. If the appellant requests this determination and submits appropriate supporting documentation, the review panel would make this determination in writing no later than 60 days after receiving the request. A review panel would consist of a panel of three members who are ALJs, members of the DAB, or qualified individuals associated with a QIC or other independent entity designated by the Secretary to make these determinations. The determination by the review panel would be considered a final decision and not subject to review by the Secretary. Given such a determination or a failure to make the determination within the 60-day deadline, the appellant would be able to request judicial review before a civil court. The filing deadline for this civil action would be within 60 days of the determination or within 60 days of the end of the deadline to make such determination. The venue for judicial review would be the U.S. District Court where the appellant is located, or where the greatest number of appellants are located, or in the district court for the District of Columbia. The amount in controversy would be subject to annual interest beginning on the first day of the first month beginning after the 60-day deadline for filing. Interest would be equal to the rate of interest on obligations issued for purchase by the Medicare trust funds effective for the month that the civil action is authorized to commence. The interest payments would not be deemed to be Medicare reimbursement.

Effective Date. See section (c).

(b) Application to Provider Agreement Determinations

Current Law. Section 1866(h) of the Social Security Act provides for a hearing and for judicial review of that hearing for any institution or agency dissatisfied with a determination that it is not a provider (or that it can no longer be a provider).

Explanation of Provision. An agency or institution's appeal concerning program participation under Section 1866 would have access to expedited judicial review under Section 1869 provisions. This provision would not be construed to affect remedies applied to assure quality of care in skilled nursing facilities (under Section 1819) while such appeals are pending.

(c) Effective Date

Explanation of Provision. Amendments in the section would apply to appeals filed on or after October 1, 2004.

Reason for Change. The provisions in 402 (a–c) on expedited access to judicial review ensure that if a review board certifies that there are no material facts in dispute and that the appeals process does not have authority to resolve the question at issue, the provider, supplier, or beneficiary may take their case to court in an expedited manner. This will facilitate more prompt resolution of challenges to the underlying validity of CMS regulations and determinations. To the extent that any part of an appeal poses a factual dispute that is being adjudicated before an administrative tribunal, this provision would not authorize the severance of the legal issues from the underlying factual dispute.

(d) Expedited Review of Certain Provider Agreement Determinations

Current Law. No provision.

Explanation of Provision. The Secretary would develop and implement a process under 1866(h) to expedite provider agreement determinations including those instances where participation is terminated or other sanctions (including denials of new admissions or appointment of temporary management) against skilled nursing facilities have been imposed. Priority would be given to termination of provider agreements. Increased appropriations from the Medicare trust funds in FY2005 and subsequently would be authorized in order to (1) reduce the average time for administrative determinations on provider participation appeals by 50 percent; (2) increase the number of ALJs and their staff; and (3) educate the ALJs and their staff on long term care issues.

Effective Date. Upon enactment.

Reason for Change. Given the disruption to beneficiaries if a facility is closed, this provides for an expedited appeal concerning a termination from Medicare.

(e) Process for Reinstatement of Approval of Certain Skilled Nursing Programs

Current Law. Civil Monetary Penalties (CMPs) can be applied when a nursing home is out of compliance with the standards of care. The facility is out of compliance when it has one or more deficiencies that subject a resident to at least the potential for more than minimal harm. The CMPs can also be applied retroactively to the date of initial non-compliance. The CMPs can also be applied when a facility is currently in compliance but was not in compliance at one point in the past. The GAO stated in March of 1999 that Congress established the CMPs to create a strong incentive for facilities to maintain compliance with federal standards.

Nurse aides render most of the daily care furnished to a nursing home resident and about 60 percent of all nursing care. Nurse aides must have 75 hours of training with 16 hours in clinical training. Nursing homes that wish to sponsor a training program must obtain state approval. All states periodically review and recertify the approved nurse aide training programs. According to the Office of the Inspector General, inadequate levels of staffing are one of the major problems with nursing homes. In particular, more nurse aide staffing can address problems, such as poor hygiene.

The law requires suspension of the nurse aide training program if the facility has been assessed a civil monetary penalty of not less than $5,000. The suspension of the training program is also secondary to the CMPs, to the extent that during an appeal of the CMPs, the nurse aide training program can continue over the 2 to 3 years required to complete the appeal.

Explanation of Provision. The Secretary is required to develop a process for the reinstatement of the nurse aide program before the end of the mandatory 2-year suspension for those facilities that have corrected any deficiencies. The Secretary must certify, in coordination with the state and after public notice and comment by beneficiaries and their advocacy groups, that the facility is in compliance and has remedied any deficiencies. An exception already exists for facilities in rural areas without any nearby nursing facili-

ties, which allows them to have their aides trained in the facility by outside nurses.

Effective Date. Upon enactment.

Reason for Change. This penalty is applied automatically in conjunction with CMPs with no Secretarial discretion. This provision provides much needed Secretarial discretion so that the Secretary can impose CMPs but permit nurse training to resume if deficiencies have been corrected and the facility is back in compliance. Under the current law, the suspension can be wholly unrelated to any quality problems or any problems with the training program. The link between any actual problem and the suspension of the training program is weak because this penalty is suspended during the 2 to 3 year process of the appeal of a CMP. There appears to be no direct evidence from OIG or GAO studies that this penalty is critical to enforcement rather it is the CMPs that are the key. Indeed, this penalty is so severe that it may deter the use of CMPs. While immediate correction of any deficiencies is required by CMS after a survey, the review process will encourage continued compliance, which has been a significant problem with nursing homes.

Section 403. Revisions to Medicare Appeals Process

(a) Requiring Full and Early Presentation of Evidence

Current Law. No provision.

Explanation of Provision. A provider or supplier would not be able to introduce evidence that was not presented at reconsideration conducted by the QIC unless a good cause precluded its introduction at or before that reconsideration.

Effective Date. On or before October 1, 2004.

Reason for Change. The Office of Inspector General identified this change as a priority to promote more expeditious resolution of appeals of denied claims. This provision requires prompt introduction of evidence relevant to a provider appeal. When deciding whether there is good cause to introduce new evidence, the adjudicator should ensure, after consideration of the totality of the circumstances, that disallowing the introduction of such new evidence would unfairly prejudice the case. The totality of the circumstances may include, but is not limited to, the following: evidence is not yet available; the appellant was not represented at a lower level of appeal; the appellant was not aware of her rights; or the appellant did not understand the proceeding.

(b) Use of Patients' Medical Records

Current Law. BIPA established QIC reconsiderations as part of the Medicare's administrative review process. To reconsider whether a service is reasonable and necessary, a QIC will employ panel of physicians or other appropriate health care professionals to review the facts and the circumstances of the initial determination. The QIC reconsideration is to be based on applicable information, including clinical experience, and medical, technical, and scientific evidence.

Explanation of Provision. Medical records of the individual involved in the appeal would be included as part of the applicable information used by QICs in their reconsideration process.

Effective Date. Upon enactment.

Reason for Change. In the determination of whether an item or service is reasonable and necessary for an individual, a beneficiary's medical records should be considered with other relevant information.

(c) Notice Requirements for Medicare Appeals

Current Law. Section 521 of BIPA (which is not yet implemented) amends Section 1869 appeals process in its entirety, but did not establish specific notice requirements for each part of the Medicare appeals process.

Explanation of Provision. The provisions would establish that a written notice of an initial determination associated with a claims denial be provided. The notice would include: (1) the reason for the denial and, upon request, the specific policy, manual or regulation used to make the decision; (2) the procedures for obtaining additional information concerning the determination; and (3) notification of appeal rights and associated instructions.

The provisions would amend the existing requirement that a reconsideration decision be written and establish that the decision would have to be provided in printed form and written in a manner that could be understood by the beneficiary; the notice would include: as appropriate, a summary of the clinical or scientific evidence used to make the decision; upon request, the policy manual or regulation used to make the decision; and a detailed explanation of the decision to the extent appropriate. The requirement that the reconsideration decision include a notice of appeal rights and relevant instructions would also be established.

Comparable requirements would be extended to ALJ decisions. These decisions would have to be written in an understandable manner and include the specific reasons for the decision, an appropriate summary of the evidence, the procedures for obtaining additional information about the decision, and a notification of appeal rights and instructions.

The current requirements that a QIC prepare documentation and an explanation of the issues for an appeal to an ALJ would be modified: a QIC would be required to submit the information required in an appeal of a Medicare contractor's decision to the ALJ.

Effective Date. Upon enactment.

Reason for Change. Currently, Medicare only provides beneficiaries with a brief statement about the initial determination of her claim on the Medicare Summary Notice. This provision provides additional information to beneficiaries (or providers who appeal on their behalf) about Medicare's denial of their claim for benefits; the reasons for the denial, and the rights to further appeal so that beneficiaries can have a clear and concise understanding of decisions affecting their medical care.

(d) Qualified Independent Contractors

Current Law. BIPA established Qualified Independent Contractor (QIC) reconsiderations as part of Medicare's administrative review process. A QIC is an entity or organization that is independent of any organization under contract with the Secretary that makes initial determinations and that meets the established requirements for sufficient training and expertise in medical science and legal matters to make such reconsiderations. QIC reviews in-

clude consideration of the facts and circumstances by a panel of physicians or appropriate health professionals. No physician or health care professional employed by a QIC may review determinations regarding services provided to a patient, if directly responsible for furnishing the services to that patient. Review of home health care services is also prohibited by physicians and other professionals who have a significant direct or indirect financial interest in the agency or institution providing the care. This prohibition extends to physicians and professionals who have family members with such significant financial interests.

Explanation of Provision. To qualify as a QIC, an entity would be required to have sufficient medical, legal and other expertise, including knowledge of the Medicare program as well as sufficient professional qualifications, independence and staffing to make reconsideration decisions. A QIC would be required to assure that reviewers meet qualification and compensation requirements. If a reconsideration request indicates that a physician furnished the item or service, a reviewing professional should be a physician. Entities and their professional reviewers would have to meet independence requirements and may not: (1) be a related party; (2) have a material familial, financial, or professional relationships with a related party; or (3) have a conflict of interest with respect to a related party. QIC's compensation would not be contingent on any decision by the QIC or by any reviewing professional. A reviewer's compensation would not be contingent on any decision rendered by the reviewer. In this context, a related party to a Medicare case involving an individual beneficiary is (1) the Secretary, the Medicare administrative contractor involved, any fiduciary, officer, director or employee of HHS or such Medicare contractor; (2) the individual or authorized representative; (3) the health professional, institution or entity that provides or manufactures the item or service involved in the case; and (4) any other party with substantial interest in the case, as defined by regulation.

Individuals affiliated with a fiscal intermediary, carrier or other contractor would be able to act as a QIC reviewer if (1) a individual is not involved with the provision of the item or service of the case; (2) individual is not an employee of the Medicare contractor and does not provide services exclusively or primarily to or on behalf of the contractor; and (3) the fact of the relationship is disclosed to the Secretary and the Medicare beneficiary or authorized representative who do not object. Individuals with staff privileges at the institution where treatment occurs would be able to serve as a reviewer if the affiliation is disclosed and there is no objection. Each reviewing professional shall be a allopathic or osteopathic physician or health care professional who is legally authorized to furnish items and services that are the subject of review in one or more states; and has medical expertise in the appropriate field for the case.

The provision would reduce the minimum number of QICs from twelve to a sufficient number, not fewer than four, to conduct reconsiderations consistent with established time frames for appeals.

Effective Date. As if included in BIPA.

Reason for Change. The BIPA 2000 law laid out broad provisions for revision of the Medicare appeals process. These provisions strengthen the appeals process by enhancing the criteria related to

the independence and expertise of the reviewers and review entities.

Section 404. Prepayment Review

Current Law. No provision.

Explanation of Provision. Medicare administrative contractors would be able to conduct random prepayment reviews in order to develop contractor-wide or program-wide claims payment error rates or under additional circumstances as established by regulations that are developed in consultation with providers and suppliers. Medicare administrative contractors would be permitted to conduct random prepayment reviews in accordance with a standard protocol developed by the Secretary. The Secretary would not be able to initiate non-random prepayment review based on the initial identification by a provider or supplier of an improper billing practice unless there is a likelihood of sustained or high level of payment error. The Secretary would be required to issue regulations relating to the termination, including termination dates, of non-random prepayment review. Such regulations may vary such a termination date based upon the differences in the circumstances triggering prepayment reviews. No provision would prevent the denial of payment for claims actually reviewed under random prepayment review. These provisions would be applied to fiscal intermediaries and carriers.

Effective Date. No later than one year from enactment. The Secretary would be required to issue regulations before that deadline; the random prepayment review protocols would apply to reviews after a date specified by the Secretary (but no later than one year from enactment.)

Reason for Change. These provisions build greater consistency and predictability into Medicare's rules for prepayment review, while protecting program integrity.

Section 405. Recovery of Overpayments

Current Law. No provision with respect to repayment plans. Section 1833(j) of the Social Security Act provides that interest accrues on underpayments or overpayments starting within 30 days of the date of the final determination of the accurate payment amount.

Explanation of Provision. Subject to certain qualifications, in circumstances where refund of an overpayment within 30 days would constitute a hardship, providers and suppliers on request would be allowed to repay the overpayment amount (by offset or otherwise) over a period of at least six months up to three years when their obligation exceeds a ten percent threshold of their annual payments from Medicare. The Secretary would be able to establish a repayment period of up to five years in cases of extreme hardship. Interest would accrue on the balance through the repayment period. The Secretary would be required to establish a process under which newly-participating providers and suppliers could qualify for a repayment plan under this hardship provision. Previous overpayment amounts already included in an ongoing repayment plans would not be included in the calculation of the hardship threshold. The Secretary would be allowed to seek immediate collection if payments are not made as scheduled. Exceptions to this provision would be permitted in cases where the Secretary has reason to sus-

pect that bankruptcy may be declared or that the provider or supplier may otherwise cease to do business or discontinue participating in the Medicare program. This subparagraph shall not apply if the Secretary has reason to suspect that false claims, fraud or abuse have been committed against the program. This provision would not affect the application of existing no-fault provisions which preclude recovery under certain circumstances where incorrect payment has been made to an individual who is without fault or where the recovery would decrease payments to another person who is without fault.

Upon enactment, the Secretary would not be able to initiate any recovery action if the provider or supplier has sought a reconsideration of the Medicare overpayment by a qualified independent contractor (QIC) until the date of the reconsideration decision. If QIC's are not yet in place, the recovery would not be initiated until the date of a redetermination decision by a fiscal intermediary or a carrier. If monies have been offset or repaid, the Secretary would return those amounts plus applicable interest if the original overpayment determination is reversed. If such an overpayment determination is upheld, interest would accrue beginning on the date of the original overpayment notice; the interest amount would be the rate otherwise applicable for Medicare overpayments.

Not later than one year after enactment, a Medicare contractor would not be able to use extrapolation to make overpayment determinations initiated after the date of enactment, unless, as determined by the Secretary, a sustained or high level of payment error exists or a documented educational intervention did not correct the payment error.

Where providers and suppliers have previously been overpaid, Medicare contractors would be able to require periodic production of records or supporting documentation for a limited sample of submitted claims to ensure that a previous practice has been discontinued.

The Secretary would be able to use a consent settlement to resolve a projected overpayment. Before entering into any consent settlements after the date of enactment, the Secretary would be required to communicate to a provider or supplier that based on a preliminary evaluation of a medical records review, an overpayment may exist; the nature of the identified problems; and the necessary steps to address the problem. The Secretary would provide 45-days where additional information may be submitted concerning the claims for which the medical records have been reviewed. After considering the additional information, the Secretary would provide notice and explanation of any remaining overpayment determination and would offer the opportunity for a statistically valid random sample (which would not waive appeal rights) or a consent settlement (based on a smaller sample with a waiver of appeal rights) to resolve the overpayment amounts.

Not later than one year after enactment, the Secretary would be required to establish, in consultation with health care associations, a process where classes of providers and suppliers are notified that their Medicare contractor has identified specific billing codes that may be over-utilized.

For audits initiated after enactment, Medicare contractors would be required to provide a written notice (which may be in electronic

form) of the intent to conduct a post-payment audit to those selected as audit candidates. Medicare contractors would be required to provide those who have been audited a full review and understandable explanation of the findings that: (1) permits the development of an appropriate corrective action plan; (2) provides information on appeal rights as well as consent settlements (which are at the discretion of the Secretary); and (3) provides for an opportunity to supply additional information to the contractor. Medicare contractors would be required to take into account the information provided on a timely basis. The provisions requiring notice of audit and findings would not apply if pending law enforcement activities would be compromised or findings of law enforcement-related audits would be revealed.

Not later than one year after enactment, the Secretary would be required to establish a standard methodology for Medicare contractors to use in selecting a claims sample for a review of abnormal billing patterns.

These provisions would apply to Medicare administrative contractors including fiscal intermediaries and carriers as well as those eligible entities with MIP contracts. These provisions do not apply to actions taken by the Department of Justice.

Effective Date. Upon enactment.

Reason for Change. These provisions build greater consistency and predictability into Medicare's rules for recovery of overpayments, while protecting program integrity.

Section 406. Provider Enrollment Process; Right of Appeal

Current Law. Providers and, to some extent suppliers, have access to certain appeal mechanisms if their application to participate in Medicare is denied or terminated. Section 1866(h) of the Social Security Act provides for a hearing and for judicial review of that hearing for any institution or agency dissatisfied with a determination that it is not a provider (or that it can no longer be a provider). There is no statutory provision extending such judicial appeal rights to suppliers. Sections 1128(a) and (b) of the Act provide for the exclusion of certain individuals or entities because of the conviction of crimes related to their participation in Medicare; Section 1128(f) provides for hearing and judicial review for exclusions. In 1999, the Health Care Financing Administration (HCFA—now the Centers for Medicare and Medicaid Services or CMS) published a proposed regulation that would revise existing Medicare Part B administrative appeals procedures and extend them to all suppliers not currently covered.

Explanation of Provision. The Secretary would be required to (1) establish by regulation an enrollment process for providers and suppliers which would include deadlines for actions on enrollment applications within six months of enactment; (2) monitor the performance of Medicare administrative contractors in meeting the deadlines: (3) consult with providers and suppliers in making changes to the enrollment forms made on or after January 1, 2004. In establishing an enrollment process for providers and suppliers, the Secretary would build upon existing Medicare practice.

Providers and suppliers whose application to enroll or reenroll has been denied and who are dissatisfied with the determination would be entitled to a hearing and judicial review of the determina-

tion under the procedures that currently apply to providers. This provision would apply to denials after a date specified by the Secretary which could not be later than one year from enactment.

Effective Date. Upon enactment.

Reason for Change. This provision gives providers and suppliers an opportunity to appeal denials of their applications to participate in the Medicare program.

Section 407. Process for Correction of Minor Errors and Omissions Without Pursuing Appeals Process

Current Law. No provision.

Explanation of Provision. The Secretary would be required to develop, in consultation with appropriate Medicare contractors and health care associations, a process where minor claims errors and omissions can be corrected and resubmitted without appealing the claims denial. In addition, a hospital may submit corrected or supplemented data for applications under 1886(d)(10)(C)(i)(II).

Effective Date. Upon enactment.

Reason for Change. Many of the providers and suppliers who testified before the Subcommittee or contacted members directly emphasized the need to create a process in which they could correct claims or other forms that were denied because they were incomplete or contained minor errors without having to pursue a formal appeal. This provision instructs the Secretary to create such a process, which will alleviate pressure on the appeals system. The Committee would be concerned, however, if this process were to become an incentive for providers to knowingly or negligently submit incomplete information.

The Committee intends that the process for correction of minor errors and omissions on claims cover both the submission of prepayment and post-payment review claims. For example, if in the case of a home health claim, the physician has signed the plan of care and/or physician's order but has not dated it, the claim shall be returned to the home health agency and may be resubmitted by the home health agency with any incomplete or missing information without having to appeal the claim. At the same time, past errors and omission in the data as part of applications under 1886(d)(10)(C)(i)(II) should not prevent a reexamination of the data in the normal application process given the significant financial consequences for any individual hospital.

Section 408. Prior Determination Process for Certain Items and Services; Advance Beneficiary Notices

Current Law. Medicare law prohibits payment for items and services that are not medically reasonable and necessary for the diagnosis or treatment of an illness or an injury. Under certain circumstances, however, Medicare will pay for non-covered services that have been provided if both the beneficiary and the provider of the services did not know and could not have reasonably been expected to know that Medicare payment would not be made for these services.

However, in most circumstances either the beneficiary or the provider will be liable in the event that Medicare does not cover an item or service. There are detailed rules on beneficiary and provider liability in the statute. A provider may be held liable for pro-

viding uncovered services, if, for example, specific requirements are published by the Medicare contractor or the provider has received a denial or reduction of payment on the same or similar service. In cases where the provider believes that the service may not be covered as reasonable and necessary, the provider may limit his liability by providing an acceptable advance notice of Medicare's possible denial of payment to the patient. The notice must be given in writing, in advance of providing the service; include the patient's name, date and description of service as well as reasons why the service would not be covered; and must be signed and dated by the patient to indicate that the beneficiary will assume financial liability for the service if Medicare payment is denied or reduced. Currently, when there is a question about coverage, there is no way for a beneficiary or provider to find out in advance whether or not Medicare will cover that item or service for that particular beneficiary.

Explanation of Provision. The Secretary would be required to establish a process through regulation where physicians and beneficiaries can establish whether Medicare covers certain items and services before such services are provided. An eligible requestor would be either a physician or a Medicare beneficiary who receives an advance beneficiary notice (ABN) from a physician. Eligible items and services for review are those physicians' services under 1848(f)(4)(A) for which a physician may be paid directly. The provisions would establish: (1) such prior determinations would be binding on the Medicare contractor, absent fraud or misrepresentation of facts; (2) the right to redetermination in the case of a denial; (3) the applicability of existing deadlines with respect to those redeterminations; (4) contractors' prior determinations (and redeterminations) are not subject to further administrative or judicial review; and (5) an individual retains all rights to usual administrative or judicial review after receiving the service or receiving a determination that a service would not be covered. This section also requires that whenever a physician requests a pre-service determination (or redetermination), beneficiaries must still receive notices that include information explaining the beneficiary's right to receive the service and request access to the appeals process under section 1869. The calculation of the sustainable growth rate for physician updates is modified so that the increase in utilization from this provision is included. These provisions would not affect a Medicare beneficiary's rights in any future appeal or judicial action. The Secretary must establish the process to allow for the processing of such requests beginning 18 months after enactment. The Secretary would be required to collect data on the advance determinations and to establish a beneficiary and provider outreach and education program. GAO is required to report on the use of the advance beneficiary notice and prior determination process within 18 months of its implementation.

Effective Date. Upon enactment.

Reason for Change. The Committee believes that when there is a question of whether Medicare will cover certain care for a beneficiary, the beneficiary should have the right to find out what will be covered before getting the service and risking financial liability. Doctors also should be able to make such a request on behalf of a particular patient. This provision is particularly important for sen-

iors and disabled individuals who tend to be risk adverse and live on fixed incomes.

E. TITLE V—MISCELLANEOUS PROVISIONS

Section 501. Policy Development Regarding Evaluation and Management (E&M) Documentation Guidelines

Current Law. No provision.

Explanation of Provision. The Secretary would not be permitted to implement any new documentation guidelines on or after enactment for evaluation and management (E&M) physician services unless the guidelines (1) are developed in collaboration with practicing physicians (both generalists and specialists) after assessment by the physician community; (2) based on a plan with deadlines for improving use of E&M codes; (3) are developed after completion of the pilot projects to test modifications to the codes; (4) are found to meet the desired objectives; and (5) are preceded the establishment of an appropriate outreach and education of the physician community. The Secretary would make changes to existing E&M guidelines to reduce paperwork burdens on physicians. The Secretary would be required to modify E&M guidelines to: (1) identify clinically relevant documentation; (2) decrease non-clinically pertinent documentation; (3) increase the reviewers' accuracy; and (4) educate the physicians and the reviewers.

The provisions would establish different pilot projects in specified settings that would be: (1) conducted on a voluntary basis in consultation with practicing physicians (both generalists and specialists); (2) be of sufficient length to educate physicians and contractors on E&M guidelines and (3) allow for an assessment of E&M guidelines and their use. A range of different projects would be established and include at least one project that (1) uses a physician peer review method; (2) uses an alternative method based on face-to-face encounter time with the patient; (3) is in a rural area; (4) is outside a rural area; and (5) involves physicians billing in a teaching setting and nonteaching setting. The projects would examine the effect of modified E&M guidelines on different types of physician practices in terms of the cost of compliance. Data collected under these projects would not be the basis for overpayment demands or post-payment audits. This protection would apply to claims filed as part of the project, would last the duration of the project, and would last for as long as the provider participated in the project. The Secretary, in consultation with practicing physicians including those in groups practices as well as generalists and specialists, would be required to evaluate the development of alternative E&M documentation systems with respect to administrative simplification requirements and report results of the study to Congress by October 1, 2005. The Medicare Payment Advisory Commission would conduct an analysis of the results of this study and submit a report to Congress.

The Secretary would be required to conduct a study of the appropriate coding of extended office visits where no diagnosis is made and submit a report with recommendations to Congress no later than October 1, 2005.

Effective Date. Upon enactment.

Reason for Change. This provision is designed to promote greater consultation with practicing physicians with regard to the complicated evaluation and management and coding requirements governing Medicare payment for physician services.

Section 502. Improvement in Oversight of Technology and Coverage

(a) Council for Technology and Innovation

Current Law. No provision.

Explanation of Provision. The Secretary is required to establish a Council for Technology and Innovation within the Centers for Medicare and Medicaid Services (CMS). The council would be composed of senior CMS staff with an Executive Coordinator, who is designated or appointed by the Secretary and reports to the CMS administrator. The Chairperson would serve as a single point of contact for outside groups and entities regarding Medicare coverage, coding, and payment processes. The Council would coordinate Medicare's coverage, coding, and payment processes as well as information exchange with other entities with respect to new technologies and procedures, including drug therapies.

Effective Date. Upon enactment.

Reason for Change. CMS personnel responsible for coverage, coding and payment of medical innovation are often not well coordinated. This provision creates a focal point for technology and innovation within the Centers for Medicare and Medicaid Services by creating a Council to coordinate across the different Centers and Offices with responsibilities in this area. The Executive Coordinator also provides a single point of contact for outside groups, similar to recent initiatives launched by the Secretary for specific issues and types of providers.

(b) Methods for Determining Payment Basis for New Lab Tests

Current Law. Outpatient clinical diagnostic laboratory tests are paid on the basis of area wide fee schedules. The law establishes cap on the payment amounts that is currently set at 74 percent of the median for all fee schedules for that test. The cap is set at 100 percent of the median for tests performed after January 1, 2001 that the Secretary determines are new tests for which no limitation amount has previously been established.

Explanation of Provision. The Secretary would be required to establish procedures (by regulation) for determining the basis and amount of payments for new clinical diagnostic laboratory tests. New laboratory tests would be defined as those assigned a new Health Care Procedure Coding System (HCPCS) code on or after January 1, 2005. The Secretary, as part of this procedure, would be required to: (1) provide a list (on an Internet site or other appropriate venue) of tests for which payments are being established in that year; (2) publish a notice of a meeting in the Federal Register on the day the list becomes available; (3) hold the public meeting no earlier than 30 days after the notice to receive public comments and recommendations; (4) take into account the comments, recommendations and accompanying data in both proposed and final payment determinations. The Secretary would set forth the criteria for making these determinations; make public the available data

considered in making such determinations; and could convene other public meetings as necessary.

Effective Date. Upon enactment.

Reason for Change. The Secretary of Health and Human Services is required to establish by regulation an open process for any clinical diagnostic laboratory test. Under the regulations, the Secretary shall develop criteria for use in determining whether a laboratory test should be established through gap-filling or cross-walking to an existing code. When existing services are not sufficient and gap filling must be used, the criteria shall explain the basis of the data, the collection of the data, and the methodology for computing the rate. It is the view of the Committee that, in these cases, it is not appropriate for carriers or the agency to substitute the payment amount of an alternative test for the gap-fill amount.

The intent of Congress is to open the process to allow CMS to have access to information from beneficiaries, physicians, health care experts and laboratories. Using the information it receives through this new process, CMS shall develop and make available to the public the information used to arrive at a final determination. The information will include the rationale for each such determination, the data on which the determination is based, and responses to public comments.

(c) Report on Improvements in External Data Collection for Use in the Medicare Inpatient System

Current Law. No provision.

Explanation of Provision. No later than October 1, 2004, the Comptroller would submit to Congress a study that analyzes the collection of external data for in computing data for inpatient hospital services. This should include a survey of data sources such as the Department of Labor, or U.S. or foreign sales information.

Effective Date. Upon enactment.

Reason for Change. The Committee is soliciting expert review from GAO on implications of flexible application of the Medicare conditions of participation for home health agencies.

(d) Process for Adoption of ICD Codes as Data Standard

Current Law. No provision.

Explanation of Provision. The provision permits the Secretary to adopt the updated version of the ICD–10 procedure and classification codes if the National Committee on Vital and Health Statistics (NCVHS) has not made a recommendation to the Secretary with respect to the adoption of these codes.

Effective Date. Upon enactment.

Reason for Change. ICD–10 is more clinically accurate and specific than ICD–9 and has been adopted by every developed country in the world. The International Classification of Disease (ICD–9) coding system was adopted in 1979 and remains in effect for procedure and diagnosis coding in the hospital inpatient setting and for reporting diagnosis codes in the hospital outpatient departments and physician offices. The NCVHS began investigating adoption of an updated coding system—ICD–10—in 1990. As part of HIPAA in 1996, Congress required NCVHS to make a recommendation on adoption prior to Secretarial approval. To date, NCVHS still has not issued a recommendation.

The current ICD–9 code system has run out of codes. As a result there are several distinct procedures performed in different parts of the body that have widely different resource utilization that are grouped together under the same procedure code. For example, code 99.29, Injection or infusion of other therapeutic or prophylactic substance, has been used to report a wide variety of procedures such as: an injection of epinephrine to cauterize a rectal ulcer, infusion of a narcotic into a pump for pain relief, insertion of an implant in the eye for slow release of an antiviral drug, and injection into the uterine artery to treat a fibroid. Such vagueness in coding hampers the program in detecting fraud and from knowing what services are being delivered to Medicare beneficiaries. Last year, CMS did find 100 unused codes under the eye and ear section of ICD–9, which is an imperfect albeit necessary solution given the lack of clinical coherence and potential confusion for coders. The timing of moving to ICD–10 is critical given that less than 75 codes remain and installation of the new procedure and diagnosis codes by hospitals will take at least 2 years. In the meantime, new initiatives for public health as well as bioterrorism are severely compromised by the lack of codes. For example, no code was available for the anthrax attack in 2001. Finally, the continued use of inappropriate and ill-defined codes in ICD–9 makes the program vulnerable to fraud and abuse. The specificity of ICD–10 will make it easier for coders to avoid mistakes and for the program to check for fraud.

Section 503. Treatment of Hospitals for Certain Services Under the Medicare Secondary Payor (MSP) Provisions

Current Law. In certain instances when a beneficiary has other insurance coverage, Medicare becomes the secondary insurance. Medicare Secondary Payor is the Medicare program's coordination of benefits with other insurers. Section 1862(b)(6) of the Social Security Act requires an entity furnishing a Part B service to obtain information from the beneficiary on whether other insurance coverage is available.

Explanation of Provision. The Secretary would not require a hospital or a critical access hospital to ask questions or obtain information relating to the Medicare secondary payor provisions in the case of reference laboratory services if the same requirements are not imposed upon those provided by an independent laboratory. Reference laboratory services would be those clinical laboratory diagnostic tests and interpretations of same that are furnished without a face-to-face encounter between the beneficiary and the hospital where the hospital submits a claim for the services.

Effective Date. Upon enactment.

Reason for Change. Hospitals would not have to directly contact each beneficiary on their retirement date, black lung status and other insurance information for reference laboratory services. While current law provisions for a claim containing valid insurance information are maintained, this provision is intended to reduce the amount of paperwork and regulatory burden related to the provision of these reference laboratory services by hospital-based entities.

Section 504. EMTALA Improvements

Current Law. Medicare requires participating hospitals that operate an emergency room to provide necessary screening and stabilization services to a patient in order to determine whether an emergency medical situation exist prior to asking about insurance status of the patient.

Hospitals that are found to be in violation of EMTALA requirements may face civil monetary penalties and termination of their provider agreement. After a state investigation of an EMTALA complaint, the CMS Regional Office may ask their local peer review organization (PRO) to perform a 5–day review to obtain additional medical expertise. This review is discretionary. However, prior to imposing a civil monetary penalty, the Secretary is required to request that a PRO assess whether the involved beneficiary had an emergency condition that had not been stabilized and provide a report on its findings. Except in the case where a delay would jeopardize the health or safety of individuals, the Secretary provides 60-day period for the requested PRO review.

Explanation of Provision. Emergency room services provided to screen and stabilize a Medicare beneficiary furnished after January 1, 2004, would be evaluated as reasonable and necessary on the basis of the information available to the treating physician or practitioner at the time the services were ordered; this would include the patient's presenting symptoms or complaint and not the patient's principal diagnosis. The Secretary would not be able to consider the frequency with which the item or service was provided to the patient before the time of admission or visit. The Secretary shall also not count the provision of the item or service during such an admission or visit when considering the frequency with which the item or service is furnished on subsequent occasions.

The Secretary would be required to establish a procedure to notify hospitals and physicians when an EMTALA investigation is closed.

Except in the case where a delay would jeopardize the health and safety of individuals, the Secretary would be required to request a PRO review before making a compliance determination that would terminate a hospital's Medicare participation because of EMTALA violation. The current period of review for the discretionary review—5 business days—would apply for such review. The Secretary shall provide a copy of the report on its findings to the hospital or physician, consistent with existing confidentiality requirements. This provision would apply to terminations initiated on or after enactment.

Effective Date. Upon enactment.

Reason for Change. Providers have reported that some Medicare contractors are looking at final diagnoses (not presenting symptoms) in applying local medical review policies (LMRPs) that match particular tests to particular diagnoses—if a test does not match a listed diagnosis, payment is denied. Other claims are reportedly being denied based on LMRPs that set frequency limits for certain tests—if the test's use in the emergency room exceeds a frequency limit, payment is denied. In its January 2001 report entitled "The Emergency Medical Treatment and Labor Act: The Enforcement Process," the OIG recommended that CMS ensure that peer review occurs before a provider is terminated from the Medicare program

for an EMTALA violation. This section implements that recommendation, making the current discretionary PRO review process mandatory in cases that involve a question of medical judgement.

Section 505. Emergency Medical Treatment and Active Labor (EMTALA) Technical Advisory Group

Current Law. No provision.

Explanation of Provision. The Secretary would be required to establish a 19-member technical advisory group under specified requirements to review issues related to the Emergency Medical Treatment and Labor Act (EMTALA). The advisory group would include: the CMS Administrator; the OIG; four hospital representatives who have EMTALA experience, (including one person from a public hospital and two of whom have not experienced EMTALA violations) seven practicing physicians with EMTALA experience; two patient representatives; two regional CMS staff involved in EMTALA investigations; one representative from a State survey organization and one representative from a PRO. The Secretary would select qualified individuals who are nominated by organizations representing providers and patients.

The advisory group would be required to: (1) elect a member to as chairperson; (2) schedule its first meeting at the direction of the Secretary and meet at least twice a year subsequently; and (3) terminate 30 months after the date of its first meeting. The advisory group would review EMTALA regulations; provide advice and recommendations to the Secretary; solicit public comments from interested parties; and disseminate information on the application of the EMTALA regulations.

Effective Date. Upon enactment.

Reason for Change. In its January 2001 report entitled "The Emergency Medical Treatment and Labor Act: The Enforcement Process," the OIG recommended that CMS establish an EMTALA technical advisory group that includes all EMTALA stakeholders to help the agency resolve any emerging issues related to implementation of the law. Some of these current issues include specialists who refuse to service on call panels and inconsistencies between State and Federal law governing emergency medical services. In its June 2001 report entitled "Emergency Care: EMTALA Implementations and Enforcement Issues," the GAO also concluded that the establishment of a technical advisory group could help CMS work with hospitals and physicians to achieve the goals of EMTALA and avoid creating unnecessary burdens for providers. This section implements the OIG recommendation, establishing a 19-member technical advisory group within HHS.

Section 506. Authorizing Use of Arrangements To Provide Core Hospice Services in Certain Circumstances

Current Law. Hospice programs are not permitted to use services provided under arrangement to deliver core hospice services. Under arrangement services are permitted for providers delivering Part A and Part B hospital services as well for skilled nursing services. However, the originating hospital or skilled nursing facility is required to bill for the service and be responsible for the quality of care delivered by the subcontractor.

Explanation of Provision. Hospice programs may enter into arrangements with another certified hospice program to provide services. The provision for under arrangement services is limited to extraordinary or non-routine circumstances, such as unanticipated periods of staffing shortages. The originating hospice program continues to bear the legal responsibility for billing and maintaining quality of care.

In addition, hospice programs may make arrangements for highly specialized services of a registered professional nurse for non-routine and infrequent services that would be impracticable and prohibitively expensive to provide directly.

Effective Date. For hospice care provided after enactment.

Reason for Change. Hospice programs would be allowed to use personnel from other hospice programs to provide services to hospice patients. The program is given the flexibility so that a hospice program could continue to serve a patient if he or she was temporarily out of the area due to travel. Otherwise, the provision of the care to the patient might be delayed by the paperwork and requirements in starting up a new service at another agency. The program is also given the flexibility to arrange for highly specialized services of a registered professional nurse for non-routine and infrequent services that the hospice cannot reasonably provide directly. It is the intent of Congress that the originating hospice maintains control over the billing and quality of care.

Section 507. Application of OSHA Bloodborne Pathogens Standards to Certain Hospitals

Current Law. Section 1866 establishes certain conditions of participation that providers must meet in order to participate in Medicare.

Explanation of Provision. Public hospitals that are not otherwise subject to the Occupational Safety and Health Act of 1970 would be required to comply with the Bloodborne Pathogens standard under section 1910.1030 of title 29 of the Code of Federal Regulations. A hospital that fails to comply with the requirement would be subject to a civil monetary penalty, but would not be terminated from participating in Medicare.

Effective Date. Applies to hospitals as of July 1, 2004.

Reason for Change. Last year, Congress enacted legislation that requires hospitals to utilize safe needles. However, that legislation only applies to non-government hospitals. Twenty-four states have similar requirements on public hospitals. This provision would protect the health and safety of health care workers in those facilities by requiring public hospitals in the other 26 states and the District of Columbia to comply with this important standard.

Section 508. BIPA-Related Technical Amendments and Corrections

Current Law. BIPA established an advisory process for national coverage determinations where panels of experts formed by advisory committees could forward their recommendations directly to the Secretary without prior approval of the advisory committee or the Executive Committee.

Explanation of Provision. This provision makes technical corrections related to the Medicare Coverage Advisory Committee by

transferring the provisions from Title 11 to Title 18 and by removing incorrect cross references to the establishment authority.

Effective Date. As if included in BIPA.

Section 509. Conforming Authority To Waive Program Exclusion

Current Law. The Secretary is required to exclude individuals and entities from participation in Federal Health Programs who are (1) convicted of a criminal offense related to health care delivery under Medicare or under State health programs; (2) convicted of a criminal offense related to patient abuse or neglect under Federal or State law; (3) convicted of a felony relating to fraud, theft, or financial misconduct relating to a health care program financed or operated by the Federal, State or local government; or (4) convicted of a felony related to a controlled substance. At the request of a state, the Secretary is permitted to waive a program exclusion with respect to Medicare or Medicaid, but only for exclusions described in (1) above.

Explanation of Provision. The Administrator of a Federal health program would be permitted to request a waiver of a program exclusion if the exclusion of a sole community physician or source of specialized services in a community would impose a hardship. This conforming change would extend the same waiver authority currently in Medicare and Medicaid to federal health programs. In addition, waivers could be requested for Medicare, Medicaid, and federal health programs with respect to all exclusions except those related to patient abuse or neglect.

Effective Date. Upon enactment.

Reason for Change. This technical correction was requested by the Office of Inspector General.

Section 510. Treatment of Certain Dental Claims

Current Law. Under current law, providers of services and suppliers submitting claims to Medicare must be enrolled in the Medicare program. However, certain services are specifically excluded from coverage under Medicare. Under current law, no payment may be made under part A or part B of the Medicare program for any services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, except in the case of inpatient hospital services associated with the provision of these dental services if the individual's underlying medical condition and clinical status or the severity of the dental service require hospitalization.

Explanation of Provision. This provision would prohibit group health plans from requiring a Medicare claims determination for dental benefits that are specifically excluded from Medicare coverage as a condition of making a determination for coverage under the group health plan. In so doing, this provision would ensure that dentists would not have to submit claims to the Medicare program (and thus enroll in the Medicare program) when the services they are providing are clearly those that are categorically excluded from coverage. In those cases that involve or appear to involve inpatient hospital services or dental services expressly covered by Medicare, a group health plan may require the claim to be first submitted to the Medicare program.

Effective Date. Sixty days after enactment.

Reason for Change. The Committee is concerned about private insurers requiring dentists to submit claims to Medicare for non-covered services before making a determination for coverage under the group health plan. Because of this requirement, dentists have been forced to enroll in the Medicare program to submit claims for services that are categorically excluded from Medicare coverage. Dentists view Medicare's enrollment application process as overly burdensome, particularly in light of the fact that most dental services are not covered by Medicare. This provision would alleviate the enrollment burden placed on dentists providing services clearly excluded from Medicare coverage, consistent with the overarching goal of this legislation to reduce regulatory burdens.

Section 511. Furnishing Hospitals With Information To Compute DSH Formula

Current Law. No provision.

Explanation of Provision. The Secretary should furnish to hospitals the data necessary to compute the Medicaid days percentage on the Medicare cost report for the purposes of computing Medicare disproportionate share payments. It is the sense of this Committee that the Secretary has the flexibility to explore different models of dissemination of the data. For instance, in Arizona, the hospitals submit the data to the states for verification and the states forward it to the fiscal intermediaries.

Effective Date. 1 year after enactment.

Reason for Change. Hospitals have reported that it is difficult and expensive to verify their Medicaid days for use for Medicare inpatient payments. The Medicare program has experienced problems with improper payments being made due to the poor quality of the data.

Section 512. Revisions to Reassignment Provisions

Current Law. Medicare does not permit staffing companies that use independent contractors to enroll in Medicare and receive direct Medicare reimbursement for health care services rendered by independent contractor physicians. Physician staffing companies set up complicated payment arrangements to work around this limitation.

Explanation of Provision. This provision would allow entities, such as staffing companies, to enroll in Medicare and to submit bills for services provided by a physician or other person, when the entity has an arrangement with the physician or other person that includes joint and several liability for overpayment, and meets other program integrity safeguards as the Secretary determines appropriate.

Effective Date. Applies to payments made on or after one year after enactment.

Reason for Change. In a March 2003 report, GAO recommended that Congress enact legislation permitting the reassignment of benefits to staffing companies that retain contractor physicians, and requiring these companies to seek enrollment in Medicare. GAO argued that this change would enhance program integrity by allowing claims monitoring.

Section 513. Specialized Medicare+Choice Plans for Special Needs Beneficiaries

Current Law. Under current law, Medicare+Choice (M+C) programs are required to enroll all beneficiaries, regardless of their health status, and cannot exclusively enroll or specialize in care for frail elderly beneficiaries. Such requirements are intended to prevent health plans from enrolling only the healthy and avoiding the sick. Specialized plans are designed to provide coverage to the frailest beneficiaries, and are not designed to provide coverage to the entire Medicare population. One model for providing a specialized Medicare+Choice plan, Evercare, operates as a demonstration program, which is set to expire in December 2003.

Explanation of Provision. This provision would allow specialized plans for special needs beneficiaries (such as the Evercare demonstration) to become any type of M+C coordinated care plan and to limit enrollment to special needs beneficiaries. Special needs beneficiaries would be defined as those M+C eligible individuals who are institutionalized, entitled to Medicaid, or meet requirements determined by the Secretary. Enrollment in specialized M+C plans could be limited to special needs beneficiaries until January 1, 2008. The Secretary would be required to report to Congress by December 31, 2006 providing an assessment of the impact of these plans. The Secretary would be required to issue final regulations establishing requirements for special needs beneficiaries within 6 months after enactment of this legislation.

Effective Date. Upon enactment.

Reason for Change. This provision is needed to allow specialized plans for special needs beneficiaries to continue to operate under the Medicare program after a demonstration ends, by allowing these plans to limit enrollment to beneficiaries with special needs. This model of care is based on resource-intensive hands-on care coordination that is best suited for frail elderly beneficiaries. Allowing specialized plans to become any type of M+C coordinated care plan would enhance plan and beneficiary flexibility.

Section 514. Temporary Suspension of OASIS for Non-Medicare and Non-Medicaid Patients During Study and Regulatory Period

Current Law. The Conditions of Participation require collection of OASIS data for all patients but the data for non-Medicare and Non-Medicaid patients are not transmitted for use in any Federal data analysis. Medicare and Medicaid data are currently used by CMS as part of the quality measurement program.

Explanation of Provision. CMS would be required to analyze how these data could be used in quality measurement or for other assessments. After the report, CMS must go through rulemaking to propose and finalize how these data for individuals who are not insured through a public program are to be used. The collection of the data by home health agencies on other than a voluntary basis (except where it conflicts with state law) is suspended until 60 days after publication of the final rule.

Effective Date. Upon enactment.

Reason for Change. Requiring home health agencies to collect data on private pay patients imposes a significant paperwork burden upon agencies. This requirement has nothing to do with qual-

ity or documentation of Medicare or Medicare patients. More troubling, these data are not collected or used for any national assessment process. Moreover, the privately insured population differs substantially from the Medicare/Medicaid population and may use different kinds of services. The Committee believes that CMS need to analyze how these data can best be used. Moreover, the OASIS data contain very specific information on the patient, their finances and their living situation. To ensure the privacy of these individuals, Congress believes that CMS should proceed through rulemaking to demonstrate to the public that confidentiality can be maintained and allow for public comments.

Section 515. Miscellaneous Reports, Studies and Publication Requirements

(a) GAO Reports on Physician Compensation

Current Law. No provision.

Explanation of Provision. No later than 6 months from enactment, GAO would be required to report to Congress on the appropriateness of the updates in the conversion factor including the appropriateness of the sustainable growth rate (SGR) formula for 2002 and subsequent years. The report would examine the stability and predictability of the updates and rate as well as the alternatives for use of the SGR in the updates. No later than 12 months from enactment, GAO would be required to report to Congress on all aspects of physician compensation for Medicare services. The report would review alternative physician payment structures, and provide recommendations to make the current system more stable and less complex.

Effective Date. Upon enactment.

Reason for Change. The Committee is soliciting expert feedback from GAO on ways to improve Medicare's complicated system of physician payment.

(b) Annual Publication of List on National Coverage Determinations

Current Law. No provision.

Explanation of Provision. The Secretary would be required to provide, in an annual report that will be publicly available, a list of Medicare's national coverage determinations made in the previous year and include information on how to learn more about such determinations.

Effective Date. Upon enactment.

(c) Report on Applying Home Health Conditions of Participation

Current Law. No provision.

Explanation of Provision. No later than 6 months from enactment, GAO would be required to report to Congress on the implications if there were flexibility in the application of Medicare conditions of participation for home health agencies with respect to groups or types of patients who are not Medicare beneficiaries. The report would include an analysis of the potential impact of flexible application on clinical operations and recipients of home health services, and analysis of methods for monitoring quality of care provided to patients.

Effective Date. Upon enactment.

Reason for Change. The Committee is soliciting expert review from GAO on implications of flexible application of the Medicare conditions of participation for home health agencies.

(d) Report on Notices Relating to Use of Hospital Lifetime Reserve Days

Current Law. No provision.

Explanation of Provision. No later than 1 year from enactment, the Inspector General would be required to submit a report to Congress on the extent to which hospitals provide notice to beneficiaries before they use their 60 lifetime reserve days, and the appropriateness of providing a notice to beneficiaries before they completely exhaust their lifetime reserve days.

Effective date. Upon enactment.

Reason for Change. The Committee is soliciting oversight on hospital compliance with requirements to notify beneficiaries about use of their 60 lifetime reserve days, and expert opinion on the appropriateness of a new notification requirement to inform beneficiaries before they exhaust their lifetime reserve days.

(e) Clarifications and Instructions to the Secretary

First, the Committee is pleased that the Secretary has published a notice of proposed rulemaking to provide Medicare payment for clinical psychology internship training programs that would not qualify under Medicare's existing provider-operated criteria. The Committee notes that Congress has consistently urged the Secretary to initiate payment for the training of clinical psychologists since 1997. Supportive language has been included in conference reports accompanying Medicare legislation in 1999 (Report 106–479), and in 2000 (Senate Report 106–293).

The Committee is concerned, however, that a delay in the rule may mean that hospitals and institutions will reduce or eliminate psychology training programs and urges implementation of the rule as soon as possible. The Committee notes that clinical psychologists provide valuable and unique services to Medicare beneficiaries during their training. Regarding their training, clinical psychologists are distinguishable from other health care professionals in that they are the only doctoral level mental health professionals fully participating in Medicare whose clinical training is not currently reimbursed. In addition, their clinical internship training is entirely controlled, administered, supervised, evaluated, and certified by the hospital or institution, separately accredited, and distinct from any university training they receive. Clinical psychologists are hospital-based in the final stages of their training functioning in a parallel status to medical interns and residents, not medical nursing or health professional students. Where a clinical psychologist has clearly finished their educational curriculum and is training solely in the hospital setting, it is the intention of Congress that the hospital be reimbursed if that training is hospital-based.

Second, Congresses original intent on BIPA section 422(a)(2) on the dialysis composite rate has not been correctly interpreted by CMS. The intent was not to bar end stage renal disease (ESRD) composite rate exception relief for facilities that are not presently being paid under an exception to the composite rate. It is the Com-

mittee's expectation that CMS will evaluate ESRD composite rate exception requests submitted in 2002 and subsequent years by new renal dialysis facilities and existing facilities that do not have an exception.

III. VOTES OF THE COMMITTEE

In compliance with clause 3(b) of rule XIII of the Rules of the House of Representatives, the following statements are made concerning the votes of the Committee on Ways and Means in its consideration of the bill, H.R. 810.

MOTION TO REPORT THE BILL

The bill, H.R. 810, as amended, was ordered favorably reported by a roll call vote of 19 yeas to 13 nays (with a quorum being present). The vote was as follows:

Representatives	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Thomas	X			Mr. Rangel		X	
Mr. Crane	X			Mr. Stark		X	
Mr. Shaw	X			Mr. Matsui			
Mrs. Johnson	X			Mr. Levin		X	
Mr. Houghton				Mr. Cardin			
Mr. Herger	X			Mr. McDermott		X	
Mr. McCrery	X			Mr. Kleczka		X	
Mr. Camp	X			Mr. Lewis (GA)			
Mr. Ramstad	X			Mr. Neal		X	
Mr. Nussle				Mr. McNulty			
Mr. Johnson	X			Mr. Jefferson		X	
Ms. Dunn	X			Mr. Tanner		X	
Mr. Collins	X			Mr. Becerra		X	
Mr. Portman	X			Mr. Doggett		X	
Mr. English	X			Mr. Pomeroy		X	
Mr. Hayworth	X			Mr. Sandlin		X	
Mr. Weller				Ms. Tubbs Jones		X	
Mr. Hulshof	X						
Mr. McInnis							
Mr. Lewis (KY)	X						
Mr. Foley	X						
Mr. Brady	X						
Mr. Ryan	X						
Mr. Cantor							

VOTES ON AMENDMENTS

An amendment in the nature of a substitute by Chairman Thomas, was agreed to by a rollcall vote of 19 yeas to 13 nays. The vote was as follows:

Representatives	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Thomas	X			Mr. Rangel		X	
Mr. Crane	X			Mr. Stark		X	
Mr. Shaw	X			Mr. Matsui			
Mrs. Johnson	X			Mr. Levin		X	
Mr. Houghton				Mr. Cardin			
Mr. Herger	X			Mr. McDermott		X	
Mr. McCrery	X			Mr. Kleczka		X	
Mr. Camp	X			Mr. Lewis (GA)			
Mr. Ramstad	X			Mr. Neal		X	
Mr. Nussle				Mr. McNulty			
Mr. Johnson	X			Mr. Jefferson		X	
Ms. Dunn	X			Mr. Tanner		X	
Mr. Collins	X			Mr. Becerra		X	

Representatives	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Portman	X			Mr. Doggett		X	
Mr. English	X			Mr. Pomeroy		X	
Mr. Hayworth	X			Mr. Sandlin		X	
Mr. Weller				Ms. Tubbs Jones		X	
Mr. Hulshof	X						
Mr. McInnis							
Mr. Lewis (KY)	X						
Mr. Foley	X						
Mr. Brady	X						
Mr. Ryan	X						
Mr. Cantor							

A rollcall vote was conducted on the following amendments to the Chairman's amendment in the nature of a substitute.

An amendment by Mrs. Johnson to require the Center for Medicare and Medicaid Services (CMS) to evaluate within 18 months the value of collection data on non-Medicare and non-Medicaid patients, suspend the collection of OASIS data on non-Medicare and non-Medicaid patients until CMS has finalized regulations on the collection and use of such data, and would not prevent home health agencies from continuing to collect OASIA data on non-Medicare and non-Medicaid patients if they so desire, was agreed to by a roll call vote of 21 yeas to 13 nays. The vote was as follows:

Representatives	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Thomas	X			Mr. Rangel		X	
Mr. Crane	X			Mr. Stark		X	
Mr. Shaw	X			Mr. Matsui			
Mrs. Johnson	X			Mr. Levin		X	
Mr. Houghton				Mr. Cardin		X	
Mr. Herger		X		Mr. McDermott		X	
Mr. McCrery		X		Mr. Kleczka		X	
Mr. Camp		X		Mr. Lewis (GA)			
Mr. Ramstad		X		Mr. Neal		X	
Mr. Nussle		X		Mr. McNulty		X	
Mr. Johnson		X		Mr. Jefferson			
Ms. Dunn		X		Mr. Tanner		X	
Mr. Collins		X		Mr. Becerra		X	
Mr. Portman		X		Mr. Doggett		X	
Mr. English		X		Mr. Pomeroy		X	
Mr. Hayworth		X		Mr. Sandlin			
Mr. Weller		X		Ms. Tubbs Jones		X	
Mr. Hulshof							
Mr. McInnis							
Mr. Lewis (KY)		X					
Mr. Foley		X					
Mr. Brady		X					
Mr. Ryan		X					
Mr. Cantor		X					

An amendment by Mr. Camp, which would require the Secretary to develop a process for the reinstatement of the nurse aid program before the mandatory 2–year disapproval program, and require that the facility and program must be certified by the Secretary as being in compliance and having remedied any deficiencies, was agreed by a roll call vote of 19 yeas to 13 nays. The vote was as follows:

Representatives	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Thomas	X			Mr. Rangel		X	
Mr. Crane	X			Mr. Stark		X	

Representatives	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Shaw	X			Mr. Matsui			
Mrs. Johnson	X			Mr. Levin		X	
Mr. Houghton				Mr. Cardin			
Mr. Herger	X			Mr. McDermott		X	
Mr. McCrery	X			Mr. Kleczka		X	
Mr. Camp	X			Mr. Lewis (GA)			
Mr. Ramstad	X			Mr. Neal		X	
Mr. Nussle				Mr. McNulty			
Mr. Johnson	X			Mr. Jefferson		X	
Ms. Dunn	X			Mr. Tanner		X	
Mr. Collins	X			Mr. Becerra		X	
Mr. Portman	X			Mr. Doggett		X	
Mr. English	X			Mr. Pomeroy		X	
Mr. Hayworth	X			Mr. Sandlin		X	
Mr. Weller				Ms. Tubbs Jones		X	
Mr. Hulshof	X						
Mr. McInnis							
Mr. Lewis (KY)	X						
Mr. Foley	X						
Mr. Brady	X						
Mr. Ryan	X						
Mr. Cantor							

IV. BUDGET EFFECTS OF THE BILL

A. Committee Estimate of Budgetary Effects

In compliance with clause 3(d)(2) of rule XIII of the Rules of the House of Representatives, the following statement is made:

The Committee agrees with the zero budgetary estimate prepared by the Congressional Budget Office (CBO), which is included below. However, it does believe that some of the administrative costs to the agency are overstated because CMS has indicated that it is already performing some of the provisions.

B. Statement Regarding New Budget Authority and Tax Expenditures

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee states that the Committee bill would result in no increase in federal direct spending.

C. Cost Estimate Prepared by the Congressional Budget Office

In compliance with clause 3(c)(3) of rule XIII of the Rules of the House of Representatives requiring a cost estimate prepared by the Congressional Budget Office (CBO), the following report prepared by the CBO is provided.

U.S. Congress,
Congressional Budget Office,
Washington, DC, April 8, 2003.

Hon. William "Bill" M. Thomas,
Chairman, Committee on Ways and Means,
House of Representatives, Washington, DC.

Dear Mr. Chairman: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 810, the Medicare Regulatory and Contracting Reform Act of 2003.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Alexis Ahlstrom.

Sincerely,

BARRY B. ANDERSON
(For Douglas Holtz-Eakin, Director).

Enclosure.

H.R. 810–Medicare Regulatory and Contracting Reform Act of 2003

Summary: The Medicare Regulatory and Contracting Reform Act of 2003 would require the Centers for Medicare and Medicaid Services (CMS) to modify how Medicare regulations and policies are developed and enforced, and would modify the procedures used to resolve disputes involving payment for services covered by Medicare. The bill would transfer certain administrative law judges from the Social Security Administration (SSA) to the Department of Health and Human Services (HHS). It would change the procedures by which Medicare makes contracts with entities to process and pay claims, and it would place new requirements on those contractors. It would require the Secretary of HHS to conduct several demonstrations, to initiate new outreach and education programs, and to complete several studies and reports. CBO estimates that implementing H.R. 810 would cost $61 million in 2004 and $1.6 billion over the 2004–2008 period, assuming appropriation of the necessary funds.

The procedural changes required by H.R. 810 would affect spending for services covered by Medicare, which is direct spending. However, many of the bill's requirements codify existing practices, while the other requirements would cause minor increases or decreases in spending for covered services. These changes could have significant impacts on direct spending in any given year, however, CBO estimates that the net change in direct spending would be insignificant over the 2004–2013 period.

H.R. 810 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA). The requirement for public hospitals participating in the Medicare program to comply with the bloodborne pathogens standard promulgated by the Occupational Safety and Health Administration (OSHA) would have cost implications for state and local governments. However, that requirement would be a condition of participating in a voluntary federal program and thus would not be an intergovernmental mandate as defined in UMRA.

Estimated cost to the Federal Government: The following table shows the estimated authorization levels and outlays for Medicare administrative expenses under current law and under H.R. 810. Assuming appropriation of the estimated amounts, CBO estimates that implementing H.R. 810 would cost $61 million in 2004 and $1.6 billion over the 2004–2008 period. The costs of this legislation fall within budget function 570 (Medicare).

	By fiscal year, in millions of dollars—					
	2003	2004	2005	2006	2007	2008
SPENDING SUBJECT TO APPROPRIATION [1]						
Spending for Medicare administrative costs under current law:						
Estimated authorization level [2]	3,798	3,931	4,078	4,236	4,418	4,626
Estimated outlays	3,797	3,925	4,064	4,209	4,377	4,579

	By fiscal year, in millions of dollars—					
	2003	2004	2005	2006	2007	2008
Proposed changes:						
Estimated authorization level	0	68	486	396	312	328
Estimated outlays	0	61	444	405	321	327
Spending for Medicare administrative costs under H.R. 810:						
Estimated authorization level	3,798	3,999	4,564	4,632	4,730	4,954
Estimated outlays	3,797	3,986	4,508	4,614	4,698	4,906

[1] Enacting H.R. 810 also would affect direct spending, but CBO estimates there would be no significant net impact over the 2004–2013 period.
[2] The 2003 level is the amount appropriated for that year. The 2004–2008 levels are baseline projections, which assume annual adjustments for anticipated inflation.

Basis of estimate

For this estimate, CBO assumes that the legislation will be enacted July 1, 2003 and that the necessary amounts will be appropriated each year, beginning in fiscal year 2004.

Spending subject to appropriation

Implementing H.R. 810 would require increased appropriations for the administration of Medicare. In particular, the bill would increase the costs to CMS for contracting, for adjudicating appeals, for education and outreach to providers and beneficiaries, and for other activities.

Contracting Reform. Under current law, CMS contracts with fiscal intermediaries and carriers to process and pay claims, to educate providers regarding Medicare billing policy, and for other purposes. This bill would change the activities required of contractors and the methods by which CMS enters into contracts and oversees the activities or contractors. CBO estimates that these provisions would increase the cost of administering contracts and the total amount CMS spends on contracts by $37 million in 2004 and $1.3 billion over the 2004–2008 period.

Contracting Changes. H.R. 810 would direct CMS to provide incentives to contractors who meet or exceed certain performance standards. Based on information furnished by CMS, we estimate that the incentive payments would total 3 percent of operating payments to contractors, or about $250 million over the 2004–2008 period.

H.R. 810 would require CMS to competitively bid contracts with fiscal intermediaries and carriers at least every five years. CBO expects that an additional 3-to-5 full-time-equivalent employees (FTEs) at the GS–12 level would be needed throughout the period to write new competitively bid contracts. The estimate assumes that about one-quarter of the contracts would be awarded to a non-incumbent bidder, and that it would cost about $2 million to transition between contractors. CBO estimates that implementing this provision would cost about $66 million over the 2004–2008 period. CBO expects that the competitive bidding of contracts would yield savings to CMS over the long run, but that savings over the 2004–2008 period would probably not be significant.

New Contractor Activities. The bill would require contractors to respond to written requests for guidance within 45 days of receipt, and would make the response binding on the Medicare program. We expect that contractors would receive 50 percent more written requests under H.R. 810 than they would under current law, with each request costing $16 to process in 2004. This, plus the require-

ment that contractors respond to those requests within 45 days, would require contractors to hire additional employees. CBO estimates that implementing these provisions would cost $11 million in 2004 and $81 million over the 2004–2008 period.

The bill also would require contractors to monitor the accuracy of information given to providers and the timeliness of contractors' processing of providers' enrollment applications. CBO estimates that complying with these provisions would cost about $16 million over the 2004–2008 period.

Beginning in January 2005, the bill would require contractors, upon request of a beneficiary or provider, to make a determination about whether Medicare will cover a particular service or item before that service is furnished. The contractor would be required to conduct a medical review and to make the coverage decision within 45 days. CBO estimates that contractors would make about 100,000 determinations a year at an average cost of about $125 per determination (at 2005 prices). We estimate the cost of administering this program would total $44 million over the 2005–2008 period.

The bill would require contractors to create a system by which providers may resubmit claims originally submitted with errors or omissions without having to pursue payment via the appeals process. CBO estimates the cost of developing and operating systems to process these resubmitted claims would total $5 million in 2004 and $56 million over the 2004–2008 period.

The bill also would require contractors to give providers or beneficiaries, upon request, a summary of the clinical and scientific evidence used in making a determination and in making a redetermination, in the case of an appeal. CBO estimates the cost of making available scientific and clinical evidence on determinations and redeterminations would total $706 million over the 2004–2008 period.

Appeals Reform. H.R. 810 would change the processes by which Medicare adjudicates appeals by providers of payment denials and conducts compliance actions against providers. The bill would delay the date by which CMS is required to implement certain provisions of the Beneficiary Improvement and Protection Act and modify other provisions. CBO estimates that implementing these provisions would cost $9 million in 2004 and $94 million over the 2004–2008 period.

Administrative Law Judge Transfer. The bill would transfer certain law judges (ALJs) from the Social Security Administration to the Department of Health and Human Services and would permit the Secretary to hire more ALJs. CBO estimates that the costs of planning and implementing the transfer, adding ALJs, and providing the ALJs with additional training on Medicare issues would be $1 million in 2004 and would total $45 million over the 2004–2008 period.

Standardization of Compliance and Appeals Actions. The bill would also standardize existing policies regarding the use of random and non-random prepayment review, the use of extrapolation in the case of overpayments, and the offering of repayment plans in the case of overpayment. In addition, H.R. 810 would create procedures by which appellants may petition for expedited access to judicial review in federal district court in certain circumstances.

The bill also would require that judgments by administrative law judges contain the scientific evidence used in their decision, similar to the bill's requirements of contractors. CBO estimates that implementing those provisions would cost $46 million over the 2004–2008 period. These provisions would require CMS to make changes to current appeals and compliance systems but would not change the conditions under which Medicare would make payments to providers. Therefore, CBO estimates that these provisions would have no effect on direct spending.

Provider and Beneficiary Program. H.R. 810 would direct CMS to expand its programs to educate beneficiaries and providers. CBO estimates that implementing these provisions would cost $10 million in 2004 and $171 million during the 2004–2008 period.

The bill would authorize the appropriation of $25 million in 2005 and in 2006, and such sums as necessary in subsequent years, for the education of providers on Medicare billing and coding practices. H.R. 810 would direct the Secretary to conduct a demonstration with small providers and suppliers in which they can get specific help with Medicare policies, including coding and reimbursement. CBO estimates that implementing these provisions would cost $108 million over the 2004–2008 period.

H.R. 810 would require CMS to designate two ombudsmen to act as liaisons between providers and Medicare, and between beneficiaries and Medicare. CBO assumes that, in order to respond to providers' and beneficiaries' needs and complaints, the ombudsmen would require the aid of several staff members. CBO estimates the cost of implementing these provisions would be $59 million over the 2004–2008 period.

The bill would direct CMS to implement a three-year outreach demonstration in at least six locations throughout the United States. The program would involve the deployment of Medicare specialists to local Social Security Administration offices to provide beneficiaries assistance and advice regarding the Medicare program. CBO estimates that the costs of the demonstration, which would include the rental of office space, salaries for Medicare specialists, and travel, moving, and administrative expenses, would total $4 million over the 2004–2008 period.

Miscellaneous provisions. H.R. 810 contains several provisions, that CBO estimates would require additional resources to implement. These provisions would:

- Require the Secretary, the Comptroller General, and the Office of the Inspector General to conduct several studies, produce reports, and conduct evaluations.
- Require the Secretary to establish two groups, a technical group to review issues relating to the Emergency Medical Treatment and Active Labor Act and a council for technology and innovation to coordinate activities with respect to new medical technologies.
- Restrict CMS from implementing new documentation guidelines for evaluation and management services until several conditions had been met.
- Allow hospitals to submit corrected and supplementary data in order to change the geographic adjustment factor used in the calculation of payments to that hospital for Medicare services. CMS

would have to reprocess that data and would have to recalculate the geographic adjustment factors for other hospitals.

• Require CMS to provide data to hospitals for the calculation of additional payments for the care of low-income patients.

CBO estimates that conducting these activities would cost $35 million over the 2004–2008 period.

Direct spending

H.R. 810 would change the conditions under which Medicare would pay for services, would create a process to establish whether an item or service is covered prior to a beneficiary receiving the service, and would reallocate payments between hospitals. CBO estimates that enacting these provisions would have no significant effect on direct spending.

In general, if a provider is not certain whether Medicare will pay for a service or item in a particular case, there is no process under current law that enables the provider or beneficiary to find out in advance whether Medicare will pay for that service or item. In such cases, the provider may request that the beneficiary sign an advanced beneficiary notice (ABN) by which the beneficiary accepts responsibility for paying for the service if Medicare denies payment. (The provider is prohibited from charging the beneficiary if the beneficiary does not sign an ABN and Medicare subsequently denies payment.

The bill would authorize the Secretary to specify services for which the provider or beneficiary may request a coverage determination before a service is furnished. Upon receipt of such a request, the bill would require the contractor to conduct a medical review and issue a decision within 45 days. The bill would make a positive determination by a contractor binding, but it would limit the number of appeals a provider could make in the event of a negative determination by a contractor.

H.R. 810 directs the Secretary to exclude this provision as a change in law or regulation in the calculation of the sustainable growth rate (SGR) used in the calculation of physician payments under Medicare. (In general, changes in law and regulation are incorporated into the calculation of the SGR). The SGR is a self-correcting mechanism: any additional services paid for under this provision would be offset by lower physician payments in subsequent years. CBO therefore estimates that enacting this provision could affect direct spending in each year, but would not have a significant impact over the 2004–2013 period.

H.R. 810 also would allow hospitals to submit corrected wage data to qualify for higher Medicare payment rates. The increase in payments to qualifying hospitals would be offset by reductions in payment rates for all other hospitals. Therefore, CBO estimates that enacting this provision would have no effect on direct spending or receipts.

Estimated impact on state, local, and tribal governments: H.R. 810 contains no intergovernmental mandates as defined in UMRA. The requirement for public hospitals participating in the Medicare program to comply with OSHA's bloodborne pathogens standard would have cost implications for state and local governments. The current OSHA standard applies to all private-sector employers with one or more employees, as well as to federal civilian employees.

This bill would extend the requirement to all hospitals participating in the Medicare program, including state and local public hospitals. About half of the states currently have bloodborne pathogen standards that apply to these hospitals that are at least as stringent as the federal standard, and many hospitals in other states have voluntarily established comparable standards. Consequently, CBO does not expect the costs of the requirement to be significant. Any such costs would result from participating in Medicare, a voluntary federal program, and thus would not be costs of an intergovernmental mandate as defined in UMRA.

Estimated impact on the private sector: H.R. 810 contains no private-sector mandates as defined in UMRA.

Previous estimate: On April 8, 2003, CBO transmitted a cost estimate for H.R. 810 as ordered reported by the House Committee on Energy and Commerce on March 26, 2003. This version of H.R. 810 does not include a provision that would require CMS to make all interim final regulations final, whereas the version reported by the Energy and Commerce Committee does. CBO estimated implementing that provision would cost $19 million over the 2004–2018 period. However, this version of H.R. 810 includes two provisions that the Energy and Commerce version does not: one that allows hospitals to resubmit data relevant to their geographic adjustment payments, and one that requires CMS to provide hospitals with data used to calculate additional payments for the provision of services to low-income patients. CBO estimates these provisions would cost $6 million over the 2004–2008 period to implement. The costs of these provisions are included above in the "Miscellaneous Provisions" cost subtotal of $35 million over the five-year period.

Estimate prepared by: Federal costs: Alexis Ahlstrom; impact on state, local, and tribal governments: Leo Lex; impact on the private sector: Robert Nguyen.

Estimate approved by: Peter H. Fontaine, Deputy Assistant Director for Budget Analysis.

V. OTHER MATTERS REQUIRED TO BE DISCUSSED UNDER THE RULES OF THE HOUSE

A. Committee Oversight Findings and Recommendations

In compliance with clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee reports that the need for this legislation was confirmed by the oversight hearings of the Subcommittee on Health. The hearings were as follows:

The Subcommittee on Health held a series of hearings on Medicare Reform during the 107th and the 108th Congress to examine the implications of regulatory burden on seniors and providers. A list of these hearings may be found in this report in Section I. Introduction, Part C. Legislative History (Page 3).

B. Summary of General Performance Goals and Objectives

In compliance with clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, the Committee states that the primary purpose of H.R. 4954 is to create a prescription drug benefit into the Medicare program while modernizing other aspects of the program.

C. CONSTITUTIONAL AUTHORITY STATEMENT

In compliance with clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, relating to constitutional Authority, the Committee states that the Committee's action in reporting the bill is derived from Article I of the Constitution, Section 8 ("The Congress shall have power to lay and collect taxes, duties, imposts, and excises, to pay the debts and to provide for * * * the General Welfare of the United States * * *").

VI. CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

SOCIAL SECURITY ACT

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TITLE XI—GENERAL PROVISIONS, PEER REVIEW, AND ADMINISTRATIVE SIMPLIFICATION

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PART A—GENERAL PROVISIONS

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APPOINTMENT OF ADVISORY COUNCIL AND OTHER ADVISORY GROUPS

SEC. 1114. (a) * * *

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[(i)(1) Any advisory committee appointed under subsection (f) to advise the Secretary on matters relating to the interpretation, application, or implementation of section 1862(a)(1) shall assure the full participation of a nonvoting member in the deliberations of the advisory committee, and shall provide such nonvoting member access to all information and data made available to voting members of the advisory committee, other than information that—

[(A) is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section (relating to trade secrets); or

[(B) the Secretary determines would present a conflict of interest relating to such nonvoting member.

[(2) If an advisory committee described in paragraph (1) organizes into panels of experts according to types of items or services considered by the advisory committee, any such panel of experts may report any recommendation with respect to such items or services directly to the Secretary without the prior approval of the advisory committee or an executive committee thereof.]

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EXCLUSION OF CERTAIN INDIVIDUALS AND ENTITIES FROM PARTICIPATION IN MEDICARE AND STATE HEALTH CARE PROGRAMS

SEC. 1128. (a) * * *

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(c) NOTICE, EFFECTIVE DATE, AND PERIOD OF EXCLUSION.—(1) * * *

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(3)(A) * * *

(B) [Subject to subparagraph (G), in the case of an exclusion under subsection (a), the minimum period of exclusion shall be not less than five years, except that, upon the request of a State, the Secretary may waive the exclusion under subsection (a)(1) in the case of an individual or entity that is the sole community physician or sole source of essential specialized services in a community.] *Subject to subparagraph (G), in the case of an exclusion under subsection (a), the minimum period of exclusion shall be not less than five years, except that, upon the request of the administrator of a Federal health care program (as defined in section 1128B(f)) who determines that the exclusion would impose a hardship on individuals entitled to benefits under part A of title XVIII or enrolled under part B of such title, or both, the Secretary may waive the exclusion under subsection (a)(1), (a)(3), or (a)(4) with respect to that program in the case of an individual or entity that is the sole community physician or sole source of essential specialized services in a community.* The Secretary's decision whether to waive the exclusion shall not be reviewable.

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PART B—PEER REVIEW OF THE UTILIZATION AND QUALITY OF HEALTH CARE SERVICES

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FUNCTIONS OF PEER REVIEW ORGANIZATIONS

SEC. 1154. (a) * * *

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(e)(1) * * *

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[(5) In any review conducted under paragraph (2) or (3), the organization shall solicit the views of the patient involved (or the patient's representative).]

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PART C—ADMINISTRATIVE SIMPLIFICATION

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GENERAL REQUIREMENTS FOR ADOPTION OF STANDARDS

SEC. 1172. (a) * * *

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(f) ASSISTANCE TO THE SECRETARY.—In complying with the requirements of this part, the Secretary shall rely on the rec-

ommendations of the National Committee on Vital and Health Statistics established under section 306(k) of the Public Health Service Act (42 U.S.C. 242k(k)), and shall consult with appropriate Federal and State agencies and private organizations. *Notwithstanding the preceding sentence, if the National Committee on Vital and Health Statistics has not made a recommendation to the Secretary before the date of the enactment of this sentence, with respect to the adoption of the International Classification of Diseases, 10th Revision, Procedure Coding System ("ICD–10–PCS") and the International Classification of Diseases, 10th Revision, Clinical Modification ("ICD–10–CM") as a standard under this part for the reporting of services, the Secretary may adopt ICD–10–PCS and ICD–10–CM as such a standard on or after such date without receiving such a recommendation.* The Secretary shall publish in the Federal Register any recommendation of the National Committee on Vital and Health Statistics regarding the adoption of a standard under this part.

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TITLE XVIII—HEALTH INSURANCE FOR THE AGED AND DISABLED

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NOTICE OF MEDICARE BENEFITS; MEDICARE AND MEDIGAP INFORMATION

SEC. 1804. (a) * * *

(b) The Secretary shall provide information via a toll-free telephone number on the programs under this title. *The Secretary shall provide, through the toll-free number 1–800–MEDICARE, for a means by which individuals seeking information about, or assistance with, such programs who phone such toll-free number are transferred (without charge) to appropriate entities for the provision of such information or assistance. Such toll-free number shall be the toll-free number listed for general information and assistance in the annual notice under subsection (a) instead of the listing of numbers of individual contractors.*

* * * * * * *

MEDICARE BENEFICIARY OMBUDSMAN

SEC. 1807. (a) IN GENERAL.—The Secretary shall appoint within the Department of Health and Human Services a Medicare Beneficiary Ombudsman who shall have expertise and experience in the fields of health care and education of (and assistance to) individuals entitled to benefits under this title.

(b) DUTIES.—The Medicare Beneficiary Ombudsman shall—

(1) receive complaints, grievances, and requests for information submitted by individuals entitled to benefits under part A or enrolled under part B, or both, with respect to any aspect of the medicare program;

(2) provide assistance with respect to complaints, grievances, and requests referred to in paragraph (1), including—

(A) assistance in collecting relevant information for such individuals, to seek an appeal of a decision or determina-

tion made by a fiscal intermediary, carrier, Medicare+Choice organization, or the Secretary; and

(B) assistance to such individuals with any problems arising from disenrollment from a Medicare+Choice plan under part C; and

(3) submit annual reports to Congress and the Secretary that describe the activities of the Office and that include such recommendations for improvement in the administration of this title as the Ombudsman determines appropriate.

The Ombudsman shall not serve as an advocate for any increases in payments or new coverage of services, but may identify issues and problems in payment or coverage policies.

(c) WORKING WITH HEALTH INSURANCE COUNSELING PROGRAMS.—To the extent possible, the Ombudsman shall work with health insurance counseling programs (receiving funding under section 4360 of Omnibus Budget Reconciliation Act of 1990) to facilitate the provision of information to individuals entitled to benefits under part A or enrolled under part B, or both regarding Medicare+Choice plans and changes to those plans. Nothing in this subsection shall preclude further collaboration between the Ombudsman and such programs.

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PART A—HOSPITAL INSURANCE BENEFITS FOR THE AGED AND DISABLED

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CONDITIONS OF AND LIMITATIONS ON PAYMENT FOR SERVICES

Requirement of Requests and Certifications

SEC. 1814. (a) * * *

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Payment for Hospice Care

(i)(1) * * *

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(4) In the case of hospice care provided by a hospice program under arrangements under section 1861(dd)(5)(D) made by another hospice program, the hospice program that made the arrangements shall bill and be paid for the hospice care.

* * * * * * *

[USE OF PUBLIC AGENCIES OR PRIVATE ORGANIZATIONS TO FACILITATE PAYMENT TO PROVIDERS OF SERVICES]

PROVISIONS RELATING TO THE ADMINISTRATION OF PART A

SEC. 1816. [(a) If any group or association of providers of services wishes to have payments under this part to such providers made through a national, State, or other public or private agency or organization and nominates such agency or organization for this purpose, the Secretary is authorized to enter into an agreement with such agency or organization providing for the determination

by such agency or organization (subject to the provisions of section 1878 and to such review by the Secretary as may be provided for by the agreement) of the amount of the payments required pursuant to this part to be made to such providers (and to providers assigned to such agency or organization under subsection (e)), and for the making of such payments by such agency or organization to such providers (and to providers assigned to such agency or organization under subsection (e)). Such agreement may also include provision for the agency or organization to do all or any part of the following: (1) to provide consultative services to institutions or agencies to enable them to establish and maintain fiscal records necessary for purposes of this part and otherwise to qualify as hospitals, extended care facilities, or home health agencies, and (2) with respect to the providers of services which are to receive payments through it (A) to serve as a center for, and communicate to providers, any information or instructions furnished to it by the Secretary, and serve as a channel of communication from providers to the Secretary; (B) to make such audits of the records of providers as may be necessary to insure that proper payments are made under this part; and (C) to perform such other functions as are necessary to carry out this subsection. As used in this title and part B of title XI, the term "fiscal intermediary" means an agency or organization with a contract under this section.

[(b) The Secretary shall not enter into or renew an agreement with any agency or organization under this section unless—

[(1) he finds—

[(A) after applying the standards, criteria, and procedures developed under subsection (f), that to do so is consistent with the effective and efficient administration of this part, and

[(B) that such agency or organization is willing and able to assist the providers to which payments are made through it under this part in the application of safeguards against unnecessary utilization of services furnished by them to individuals entitled to hospital insurance benefits under section 226, and the agreement provides for such assistance; and

[(2) such agency or organization agrees—

[(A) to furnish to the Secretary such of the information acquired by it in carrying out its agreement under this section, and

[(B) to provide the Secretary with access to all such data, information, and claims processing operations,

as the Secretary may find necessary in performing his functions under this part.]

(a) The administration of this part shall be conducted through contracts with medicare administrative contractors under section 1874A.

(c)[(1) An agreement with any agency or organization under this section may contain such terms and conditions as the Secretary finds necessary or appropriate, may provide for advances of funds to the agency or organization for the making of payments by it under subsection (a), and shall provide for payment of so much of the cost of administration of the agency or organization as is determined by the Secretary to be necessary and proper for carrying out

the functions covered by the agreement. The Secretary shall provide that in determining the necessary and proper cost of administration, the Secretary shall, with respect to each agreement, take into account the amount that is reasonable and adequate to meet the costs which must be incurred by an efficiently and economically operated agency or organization in carrying out the terms of its agreement. The Secretary shall cause to have published in the Federal Register, by not later than September 1 before each fiscal year, data, standards, and methodology to be used to establish budgets for fiscal intermediaries under this section for that fiscal year, and shall cause to be published in the Federal Register for public comment, at least 90 days before such data, standards, and methodology are published, the data, standards, and methodology proposed to be used. The Secretary may not require, as a condition of entering into or renewing an agreement under this section or under section 1871, that a fiscal intermediary match data obtained other than in its activities under this part with data used in the administration of this part for purposes of identifying situations in which the provisions of section 1862(b) may apply.]

(2)(A) Each [agreement under this section] *contract under section 1874A that provides for making payments under this part* shall provide that payment shall be issued, mailed, or otherwise transmitted with respect to not less than 95 percent of all claims submitted under this title—

(i) * * *

* * * * * * *

(3)(A) Each [agreement under this section] *contract under section 1874A that provides for making payments under this part* shall provide that no payment shall be issued, mailed, or otherwise transmitted with respect to any claim submitted under this title within the applicable number of calendar days after the date on which the claim is received.

* * * * * * *

[(d) If the nomination of an agency or organization as provided in this section is made by a group or association of providers of services, it shall not be binding on members of the group or association which notify the Secretary of their election to that effect. Any provider may, upon such notice as may be specified in the agreement under this section with an agency or organization, withdraw its nomination to receive payments through such agency or organization. Any provider which has withdrawn its nomination, and any provider which has not made a nomination, may elect to receive payments from any agency or organization which has entered into an agreement with the Secretary under this section if the Secretary and such agency or organization agree to it.

[(e)(1) Notwithstanding subsections (a) and (d), the Secretary, after taking into consideration any preferences of providers of services, may assign or reassign any provider of services to any agency or organization which has entered into an agreement with him under this section, if he determines, after applying the standards, criteria, and procedures developed under subsection (f), that such assignment or reassignment would result in the more effective and efficient administration of this part.

[(2) Notwithstanding subsections (a) and (d), the Secretary may (subject to the provisions of paragraph (4)) designate a national or regional agency or organization which has entered into an agreement with him under this section to perform functions under the agreement with respect to a class of providers of services in the Nation or region (as the case may be), if he determines, after applying the standards, criteria, and procedures developed under subsection (f), that such designation would result in more effective and efficient administration of this part.

[(3)(A) Before the Secretary makes an assignment or reassignment under paragraph (1) of a provider of services to other than the agency or organization nominated by the provider, he shall furnish (i) the provider and such agency or organization with a full explanation of the reasons for his determination as to the efficiency and effectiveness of the agency or organization to perform the functions required under this part with respect to the provider, and (ii) such agency or organization with opportunity for a hearing, and such determination shall be subject to judicial review in accordance with chapter 7 of title 5, United States Code.

[(B) Before the Secretary makes a designation under paragraph (2) with respect to a class of providers of services, he shall furnish (i) such providers and the agencies and organizations adversely affected by such designation with a full explanation of the reasons for his determination as to the efficiency and effectiveness of such agencies and organizations to perform the functions required under this part with respect to such providers, and (ii) the agencies and organizations adversely affected by such designation with opportunity for a hearing, and such determination shall be subject to judicial review in accordance with chapter 7 of title 5, United States Code.

[(4) Notwithstanding subsections (a) and (d) and paragraphs (1), (2), and (3) of this subsection, the Secretary shall designate regional agencies or organizations which have entered into an agreement with him under this section to perform functions under such agreement with respect to home health agencies (as defined in section 1861(o)) in the region, except that in assigning such agencies to such designated regional agencies or organizations the Secretary shall assign a home health agency which is a subdivision of a hospital (and such agency and hospital are affiliated or under common control) only if, after applying such criteria relating to administrative efficiency and effectiveness as he shall promulgate, he determines that such assignment would result in the more effective and efficient administration of this title. By not later than July 1, 1987, the Secretary shall limit the number of such regional agencies or organizations to not more than ten.

[(5) Notwithstanding any other provision of this title, the Secretary shall designate the agency or organization which has entered into an agreement under this section to perform functions under such an agreement with respect to each hospice program, except that with respect to a hospice program which is a subdivision of a provider of services (and such hospice program and provider of services are under common control) due regard shall be given to the agency or organization which performs the functions under this section for the provider of services.

[(f)(1) In order to determine whether the Secretary should enter into, renew, or terminate an agreement under this section with an agency or organization, whether the Secretary should assign or reassign a provider of services to an agency or organization, and whether the Secretary should designate an agency or organization to perform services with respect to a class of providers of services, the Secretary shall develop standards, criteria, and procedures to evaluate such agency's or organization's (A) overall performance of claims processing (including the agency's or organization's success in recovering payments made under this title for services for which payment has been or could be made under a primary plan (as defined in section 1862(b)(2)(A))) and other related functions required to be performed by such an agency or organization under an agreement entered into under this section, and (B) performance of such functions with respect to specific providers of services, and the Secretary shall establish standards and criteria with respect to the efficient and effective administration of this part. No agency or organization shall be found under such standards and criteria not to be efficient or effective or to be less efficient or effective solely on the ground that the agency or organization serves only providers located in a single State.

[(2) The standards and criteria established under paragraph (1) shall include—

[(A) with respect to claims for services furnished under this part by any provider of services other than a hospital—

[(i) whether such agency or organization is able to process 75 percent of reconsiderations within 60 days (except in the case of fiscal year 1989, 66 percent of reconsiderations) and 90 percent of reconsiderations within 90 days, and

[(ii) the extent to which such agency's or organization's determinations are reversed on appeal; and

[(B) with respect to applications for an exemption from or exception or adjustment to the target amount applicable under section 1886(b) to a hospital that is not a subsection (d) hospital (as defined in section 1886(d)(1)(B))—

[(i) if such agency or organization receives a completed application, whether such agency or organization is able to process such application not later than 75 days after the application is filed, and

[(ii) if such agency or organization receives an incomplete application, whether such agency or organization is able to return the application with instructions on how to complete the application not later than 60 days after the application is filed.

[(g) An agreement with the Secretary under this section may be terminated—

[(1) by the agency or organization which entered into such agreement at such time and upon such notice to the Secretary, to the public, and to the providers as may be provided in regulations, or

[(2) by the Secretary at such time and upon such notice to the agency or organization, to the providers which have nominated it for purposes of this section, and to the public, as may be provided in regulations, but only if he finds, after applying

the standards, criteria, and procedures developed under subsection (f) and after reasonable notice and opportunity for hearing to the agency or organization, that (A) the agency or organization has failed substantially to carry out the agreement, or (B) the continuation of some or all of the functions provided for in the agreement with the agency or organization is disadvantageous or is inconsistent with the efficient administration of this part.

[(h) An agreement with an agency or organization under this section may require any of its officers or employees certifying payments or disbursing funds pursuant to the agreement, or otherwise participating in carrying out the agreement, to give surety bond to the United States in such amount as the Secretary may deem appropriate.

[(i)(1) No individual designated pursuant to an agreement under this section as a certifying officer shall, in the absence of gross negligence or intent to defraud the United States, be liable with respect to any payments certified by him under this section.

[(2) No disbursing officer shall, in the absence of gross negligence or intent to defraud the United States, be liable with respect to any payment by him under this section if it was based upon a voucher signed by a certifying officer designated as provided in paragraph (1) of this subsection.

[(3) No such agency or organization shall be liable to the United States for any payments referred to in paragraph (1) or (2).]

(j) [An agreement with an agency or organization under this section] *A contract with a medicare administrative contractor under section 1874A with respect to the administration of this part* shall require that, with respect to a claim for home health services, extended care services, or post-hospital extended care services submitted by a provider to [such agency or organization] *such medicare administrative contractor* that is denied, [such agency or organization] *such medicare administrative contractor—*

(1) * * *

* * * * * * *

(k) [An agreement with an agency or organization under this section] *A contract with a medicare administrative contractor under section 1874A with respect to the administration of this part* shall require that [such agency or organization] *such medicare administrative contractor* submit an annual report to the Secretary describing the steps taken to recover payments made for items or services for which payment has been or could be made under a primary plan (as defined in section 1862(b)(2)(A)).

[(l) No agency or organization may carry out (or receive payment for carrying out) any activity pursuant to an agreement under this section to the extent that the activity is carried out pursuant to a contract under the Medicare Integrity Program under section 1893.]

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PART B—SUPPLEMENTARY MEDICAL INSURANCE BENEFITS FOR THE AGED AND DISABLED

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PAYMENT OF BENEFITS

SEC. 1833. (a) * * *

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(h)(1) * * *

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(8)(A) The Secretary shall establish by regulation procedures for determining the basis for, and amount of, payment under this subsection for any clinical diagnostic laboratory test with respect to which a new or substantially revised HCPCS code is assigned on or after January 1, 2005 (in this paragraph referred to as "new tests").

(B) Determinations under subparagraph (A) shall be made only after the Secretary—

(i) makes available to the public (through an Internet site and other appropriate mechanisms) a list that includes any such test for which establishment of a payment amount under this subsection is being considered for a year;

(ii) on the same day such list is made available, causes to have published in the Federal Register notice of a meeting to receive comments and recommendations (and data on which recommendations are based) from the public on the appropriate basis under this subsection for establishing payment amounts for the tests on such list;

(iii) not less than 30 days after publication of such notice convenes a meeting, that includes representatives of officials of the Centers for Medicare & Medicaid Services involved in determining payment amounts, to receive such comments and recommendations (and data on which the recommendations are based);

(iv) taking into account the comments and recommendations (and accompanying data) received at such meeting, develops and makes available to the public (through an Internet site and other appropriate mechanisms) a list of proposed determinations with respect to the appropriate basis for establishing a payment amount under this subsection for each such code, together with an explanation of the reasons for each such determination, the data on which the determinations are based, and a request for public written comments on the proposed determination; and

(v) taking into account the comments received during the public comment period, develops and makes available to the public (through an Internet site and other appropriate mechanisms) a list of final determinations of the payment amounts for such tests under this subsection, together with the rationale for each such determination, the data on which the determinations are based, and responses to comments and suggestions received from the public.

(C) Under the procedures established pursuant to subparagraph (A), the Secretary shall—

(i) set forth the criteria for making determinations under subparagraph (A); and

(ii) make available to the public the data (other than proprietary data) considered in making such determinations.

(D) The Secretary may convene such further public meetings to receive public comments on payment amounts for new tests under this subsection as the Secretary deems appropriate.

(E) For purposes of this paragraph:

(i) The term "HCPCS" refers to the Health Care Procedure Coding System.

(ii) A code shall be considered to be "substantially revised" if there is a substantive change to the definition of the test or procedure to which the code applies (such as a new analyte or a new methodology for measuring an existing analyte-specific test).

* * * * * * *

[USE OF CARRIERS FOR ADMINISTRATION OF BENEFITS]

PROVISIONS RELATING TO THE ADMINISTRATION OF PART B

SEC. 1842. [(a) In order to provide for the administration of the benefits under this part with maximum efficiency and convenience for individuals entitled to benefits under this part and for providers of services and other persons furnishing services to such individuals, and with a view to furthering coordination of the administration of the benefits under part A and under this part, the Secretary is authorized to enter into contracts with carriers, including carriers with which agreements under section 1816 are in effect, which will perform some or all of the following functions (or, to the extent provided in such contracts, will secure performance thereof by other organizations); and, with respect to any of the following functions which involve payments for physicians' services on a reasonable charge basis, the Secretary shall to the extent possible enter into such contracts:

[(1)(A) make determinations of the rates and amounts of payments required pursuant to this part to be made to providers of services and other persons on a reasonable cost or reasonable charge basis (as may be applicable);

[(B) receive, disburse, and account for funds in making such payments; and

[(C) make such audits of the records of providers of services as may be necessary to assure that proper payments are made under this part;

[(2)(A) determine compliance with the requirements of section 1861(k) as to utilization review; and

[(B) assist providers of services and other persons who furnish services for which payment may be made under this part in the development of procedures relating to utilization practices, make studies of the effectiveness of such procedures and methods for their improvement, assist in the application of safeguards against unnecessary utilization of services furnished by providers of services and other persons to individuals entitled to benefits under this part, and provide procedures for and assist in arranging, where necessary, the establishment of groups outside hospitals (meeting the requirements of section 1861(k)(2)) to make reviews of utilization;

[(3) serve as a channel of communication of information relating to the administration of this part; and

[(4) otherwise assist, in such manner as the contract may provide, in discharging administrative duties necessary to carry out the purposes of this part.]

(a) The administration of this part shall be conducted through contracts with medicare administrative contractors under section 1874A.

(b)[(1) Contracts with carriers under subsection (a) may be entered into without regard to section 3709 of the Revised Statutes or any other provision of law requiring competitive bidding.]

(2)[(A) No such contract shall be entered into with any carrier unless the Secretary finds that such carrier will perform its obligations under the contract efficiently and effectively and will meet such requirements as to financial responsibility, legal authority, and other matters as he finds pertinent. The Secretary shall publish in the Federal Register standards and criteria for the efficient and effective performance of contract obligations under this section, and opportunity shall be provided for public comment prior to implementation. In establishing such standards and criteria, the Secretary shall provide a system to measure a carrier's performance of responsibilities described in paragraph (3)(H), subsection (h), and section 1845(e)(2). The Secretary may not require, as a condition of entering into or renewing a contract under this section or under section 1871, that a carrier match data obtained other than in its activities under this part with data used in the administration of this part for purposes of identifying situations in which section 1862(b) may apply.

[(B) The Secretary shall establish standards for evaluating carriers' performance of reviews of initial carrier determinations and of fair hearings under paragraph (3)(C), under which a carrier is expected—

[(i) to complete such reviews, within 45 days after the date of a request by an individual enrolled under this part for such a review, in 95 percent of such requests, and

[(ii) to make a final determination, within 120 days after the date of receipt of a request by an individual enrolled under this part for a fair hearing under paragraph (3)(C), in 90 percent of such cases.]

(C) In the case of residents of nursing facilities who receive services described in clause (i) or (ii) of section 1861(s)(2)(K) performed by a member of a team, the Secretary shall instruct [carriers] *medicare administrative contractors* to develop mechanisms which permit routine payment under this part for up to 1.5 visits per month per resident. In the previous sentence, the term "team" refers to a physician and includes a physician assistant acting under the supervision of the physician or a nurse practitioner working in collaboration with that physician, or both.

[(D) In addition to any other standards and criteria established by the Secretary for evaluating carrier performance under this paragraph relating to avoiding erroneous payments, the carrier shall be subject to standards and criteria relating to the carrier's success in recovering payments made under this part for items or services for which payment has been or could be made under a primary plan (as defined in section 1862(b)(2)(A)).

[(E) With respect to the payment of claims for home health services under this part that, but for the amendments made by section

4611 of the Balanced Budget Act of 1997, would be payable under part A instead of under this part, the Secretary shall continue administration of such claims through fiscal intermediaries under section 1816.]

(3) [Each such contract shall provide that the carrier] *The Secretary—*

(A) [will] *shall* take such action as may be necessary to assure that, where payment under this part for a service is on a cost basis, the cost is reasonable cost (as determined under section 1861(v));

(B) [will] *shall* take such action as may be necessary to assure that, where payment under this part for a service is on a charge basis, such charge will be reasonable and not higher than the charge applicable, for a comparable service and under comparable circumstances, [to the policyholders and subscribers of the carrier] *to the policyholders and subscribers of the medicare administrative contractor*, and such payment will (except as otherwise provided in section 1870(f)) be made—

(i) * * *

* * * * * * *

[(C) will establish and maintain procedures pursuant to which an individual enrolled under this part will be granted an opportunity for a fair hearing by the carrier, in any case where the amount in controversy is at least $100, but less than $500, when requests for payment under this part with respect to services furnished him are denied or are not acted upon with reasonable promptness or when the amount of such payment is in controversy;

[(D) will furnish to the Secretary such timely information and reports as he may find necessary in performing his functions under this part;

[(E) will maintain such records and afford such access thereto as the Secretary finds necessary to assure the correctness and verification of the information and reports under subparagraph (D) and otherwise to carry out the purposes of this part;]

(F) [will] *shall* take such action as may be necessary to assure that where payment under this part for a service rendered is on a charge basis, such payment shall be determined on the basis of the charge that is determined in accordance with this section on the basis of customary and prevailing charge levels in effect at the time the service was rendered or, in the case of services rendered more than 12 months before the year in which the bill is submitted or request for payment is made, on the basis of such levels in effect for the 12-month period preceding such year;

(G) [will] *shall*, for a service that is furnished with respect to an individual enrolled under this part, that is not paid on an assignment-related basis, and that is subject to a limiting charge under section 1848(g)—

(i) * * *

* * * * * * *

(H) [if it makes determinations or payments with respect to physicians' services, will] *shall* implement—

(i) programs to recruit and retain physicians as participating physicians in the area served by the [carrier] *medicare administrative contractor*, including educational and outreach activities and the use of professional relations personnel to handle billing and other problems relating to payment of claims of participating physicians; and

* * * * * * *

[(I) will submit annual reports to the Secretary describing the steps taken to recover payments made under this part for items or services for which payment has been or could be made under a primary plan (as defined in section 1862(b)(2)(A)); and]

(L) [will] *shall* monitor and profile physicians' billing patterns within each area or locality and provide comparative data to physicians whose utilization patterns vary significantly from other physicians in the same payment area or locality[;]. [and shall contain such other terms and conditions not inconsistent with this section as the Secretary may find necessary or appropriate.] In determining the reasonable charge for services for purposes of this paragraph, there shall be taken into consideration the customary charges for similar services generally made by the physician or other person furnishing such services, as well as the prevailing charges in the locality for similar services. No charge may be determined to be reasonable in the case of bills submitted or requests for payment made under this part after December 31, 1970, if it exceeds the higher of (i) the prevailing charge recognized by the carrier and found acceptable by the Secretary for similar services in the same locality in administering this part on December 31, 1970, or (ii) the prevailing charge level that, on the basis of statistical data and methodology acceptable to the Secretary, would cover 75 percent of the customary charges made for similar services in the same locality during the 12-month period ending on the June 30 last preceding the start of the calendar year in which the service is rendered. In the case of physicians' services the prevailing charge level determined for purposes of clause (ii) of the preceding sentence for any twelve-month period (beginning after June 30, 1973) specified in clause (ii) of such sentence may not exceed (in the aggregate) the level determined under such clause for the fiscal year ending June 30, 1973, or (with respect to physicians' services furnished in a year after 1987) the level determined under this sentence (or under any other provision of law affecting the prevailing charge level) for the previous year except to the extent that the Secretary finds, on the basis of appropriate economic index data, that such higher level is justified by year-to-year economic changes. With respect to power-operated wheelchairs for which payment may be made in accordance with section 1861(s)(6), charges determined to be reasonable may not exceed the lowest charge at which power-operated wheelchairs are available in the locality. In the case of medical services, supplies, and equipment (including equipment servicing) that, in the judgment of the Secretary, do not generally vary significantly in quality from one supplier to another, the charges incurred after December 31, 1972, determined to be reasonable may not exceed the lowest charge levels at which such services, supplies, and equipment are widely and consistently available in a locality except to the extent and under

the circumstances specified by the Secretary. The requirement in subparagraph (B) that a bill be submitted or request for payment be made by the close of the following calendar year shall not apply if (I) failure to submit the bill or request the payment by the close of such year is due to the error or misrepresentation of an officer, employee, fiscal intermediary, carrier, *medicare administrative contractor,* or agent of the Department of Health and Human Services performing functions under this title and acting within the scope of his or its authority, and (II) the bill is submitted or the payment is requested promptly after such error or misrepresentation is eliminated or corrected. Notwithstanding the provisions of the third and fourth sentences preceding this sentence, the prevailing charge level in the case of a physician service in a particular locality determined pursuant to such third and fourth sentences for any calendar year after 1974 shall, if lower than the prevailing charge level for the fiscal year ending June 30, 1975, in the case of a similar physician service in the same locality by reason of the application of economic index data, be raised to such prevailing charge level for the fiscal year ending June 30, 1975, and shall remain at such prevailing charge level until the prevailing charge for a year (as adjusted by economic index data) equals or exceeds such prevailing charge level. The amount of any charges for outpatient services which shall be considered reasonable shall be subject to the limitations established by regulations issued by the Secretary pursuant to section 1861(v)(1)(K), and in determining the reasonable charge for such services, the Secretary may limit such reasonable charge to a percentage of the amount of the prevailing charge for similar services furnished in a physician's office, taking into account the extent to which overhead costs associated with such outpatient services have been included in the reasonable cost or charge of the facility.

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[(5) Each contract under this section shall be for a term of at least one year, and may be made automatically renewable from term to term in the absence of notice by either party of intention to terminate at the end of the current term; except that the Secretary may terminate any such contract at any time (after such reasonable notice and opportunity for hearing to the carrier involved as he may provide in regulations) if he finds that the carrier has failed substantially to carry out the contract or is carrying out the contract in a manner inconsistent with the efficient and effective administration of the insurance program established by this part.**]**

(6) No payment under this part for a service provided to any individual shall (except as provided in section 1870) be made to anyone other than such individual or (pursuant to an assignment described in subparagraph (B)(ii) of paragraph (3)) the physician or other person who provided the service, except that (A) payment may be made (i) to the employer of such physician or other person if such physician or other person is required as a condition of his employment to turn over his fee for such service to his employer, or **[**(ii) (where the service was provided in a hospital, critical access hospital, clinic, or other facility) to the facility in which the service was provided if there is a contractual arrangement between such physician or other person and such facility under which such facil-

ity submits the bill for such service, (B) payment may be made to an entity (i) which provides coverage of the services under a health benefits plan, but only to the extent that payment is not made under this part, (ii) which has paid the person who provided the service an amount (including the amount payable under this part) which that person has accepted as payment in full for the service, and] *(ii) where the service was provided under a contractual arrangement between such physician or other person and a qualified entity (as defined by the Secretary) or other person, to the entity or other person if under such arrangement such entity or individual submits the bill for such service and such arrangement (I) includes joint and several liability for overpayment by such physician or other person and such entity or other person, and (II) meets such other program integrity and other safeguards as the Secretary may determine to be appropriate,* (iii) to which the individual has agreed in writing that payment may be made under this part, (C) in the case of services described in clause (i) of section 1861(s)(2)(K), payment shall be made to either (i) the employer of the physician assistant involved, or (ii) with respect to a physician assistant who was the owner of a rural health clinic (as described in section 1861(aa)(2)) for a continuous period beginning prior to the date of the enactment of the Balanced Budget Act of 1997 and ending on the date that the Secretary determines such rural health clinic no longer meets the requirements of section 1861(aa)(2), payment may be made directly to the physician assistant, (D) payment may be made to a physician for physicians' services (and services furnished incident to such services) furnished by a second physician to patients of the first physician if (i) the first physician is unavailable to provide the services; (ii) the services are furnished pursuant to an arrangement between the two physicians that (I) is informal and reciprocal, or (II) involves per diem or other fee-for-time compensation for such services; (iii) the services are not provided by the second physician over a continuous period of more than 60 days; and (iv) the claim form submitted to the carrier for such services includes the second physician's unique identifier (provided under the system established under subsection (r)) and indicates that the claim meets the requirements of this subparagraph for payment to the first physician, (E) in the case of an item or service (other than services described in section 1888(e)(2)(A)(ii)) furnished by, or under arrangements made by, a skilled nursing facility to an individual who (at the time the item or service is furnished) is a resident of a skilled nursing facility, payment shall be made to the facility, (F) in the case of home health services (including medical supplies described in section 1861(m)(5), but excluding durable medical equipment to the extent provided for in such section) furnished to an individual who (at the time the item or service is furnished) is under a plan of care of a home health agency, payment shall be made to the agency (without regard to whether or not the item or service was furnished by the agency, by others under arrangement with them made by the agency, or when any other contracting or consulting arrangement, or otherwise), and (G) in the case of services in a hospital or clinic to which section 1880(e) applies, payment shall be made to such hospital or clinic. No payment which under the preceding sentence may be made directly to the physician or other person providing the service involved (pursuant

to an assignment described in subparagraph (B)(ii) of paragraph (3)) shall be made to anyone else under a reassignment or power of attorney (**[**except to an employer or facility as described in clause (A)**]** *except to an employer, entity, or other person as described in subparagraph (A)* of such sentence); but nothing in this subsection shall be construed (i) to prevent the making of such a payment in accordance with an assignment from the individual to whom the service was provided or a reassignment from the physician or other person providing such service if such assignment or reassignment is made to a governmental agency or entity or is established by or pursuant to the order of a court of competent jurisdiction, or (ii) to preclude an agent of the physician or other person providing the service from receiving any such payment if (but only if) such agent does so pursuant to an agency agreement under which the compensation to be paid to the agent for his services for or in connection with the billing or collection of payments due such physician or other person under this title is unrelated (directly or indirectly) to the amount of such payments or the billings therefor, and is not dependent upon the actual collection of any such payment. For purposes of subparagraph (C) of the first sentence of this paragraph, an employment relationship may include any independent contractor arrangement, and employer status shall be determined in accordance with the law of the State in which the services described in such clause are performed.

(7)(A) In the case of physicians' services furnished to a patient in a hospital with a teaching program approved as specified in section 1861(b)(6) but which does not meet the conditions described in section 1861(b)(7), **[**the carrier**]** *the Secretary* shall not provide (except on the basis described in subparagraph (C)) for payment for such services under this part—

(i) * * *

* * * * * * *

(B) The customary charge for such services in a hospital shall be determined in accordance with regulations issued by the Secretary and taking into account the following factors:

(i) In the case of a physician who is not a teaching physician (as defined by the Secretary), **[**the carrier**]** *the Secretary* shall take into account the amounts the physician charges for similar services in the physician's practice outside the teaching setting.

(ii) In the case of a teaching physician, if the hospital, its physicians, or other appropriate billing entity has established one or more schedules of charges which are collected for medical and surgical services, **[**the carrier**]** *the Secretary* shall base payment under this title on the greatest of—

(I) * * *

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(C) In the case of physicians' services furnished to a patient in a hospital with a teaching program approved as specified in section 1861(b)(6) but which does not meet the conditions described in section 1861(b)(7), if the conditions described in subclauses (I) and (II) of subparagraph (A)(i) are met and if the physician elects payment to be determined under this subparagraph, **[**the carrier**]** *the Secretary* shall provide for payment for such services under this part

on the basis of regulations of the Secretary governing reimbursement for the services of hospital-based physicians (and not on any other basis).

* * * * * * *

(c)[(1) Any contract entered into with a carrier under this section shall provide for advances of funds to the carrier for the making of payments by it under this part, and shall provide for payment of the cost of administration of the carrier, as determined by the Secretary to be necessary and proper for carrying out the functions covered by the contract. The Secretary shall provide that in determining a carrier's necessary and proper cost of administration, the Secretary shall, with respect to each contract, take into account the amount that is reasonable and adequate to meet the costs which must be incurred by an efficiently and economically operated carrier in carrying out the terms of its contract. The Secretary shall cause to have published in the Federal Register, by not later than September 1 before each fiscal year, data, standards, and methodology to be used to establish budgets for carriers under this section for that fiscal year, and shall cause to be published in the Federal Register for public comment, at least 90 days before such data, standards, and methodology are published, the data, standards, and methodology proposed to be used.]

(2)(A) Each [contract under this section which provides for the disbursement of funds, as described in subsection (a)(1)(B),] *contract under section 1874A that provides for making payments under this part* shall provide that payment shall be issued, mailed, or otherwise transmitted with respect to not less than 95 percent of all claims submitted under this part—

(i) * * *

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(3)(A) Each contract under this section which provides for the disbursement of funds, as described in [subsection (a)(1)(B)] *section 1874A(a)(3)(B)*, shall provide that no payment shall be issued, mailed, or otherwise transmitted with respect to any claim submitted under this title within the applicable number of calendar days after the date on which the claim is received.

(4) Neither a [carrier] *medicare administrative contractor* nor the Secretary may impose a fee under this title—

(A) * * *

* * * * * * *

[(5) Each contract under this section which provides for the disbursement of funds, as described in subsection (a)(1)(B), shall require the carrier to meet criteria developed by the Secretary to measure the timeliness of carrier responses to requests for payment of items described in section 1834(a)(15)(C).

[(6) No carrier may carry out (or receive payment for carrying out) any activity pursuant to a contract under this subsection to the extent that the activity is carried out pursuant to a contract under the Medicare Integrity Program under section 1893. The previous sentence shall not apply with respect to the activity described in section 1893(b)(5) (relating to prior authorization of certain items of durable medical equipment under section 1834(a)(15)).

[(d) Any contract with a carrier under this section may require such carrier or any of its officers or employees certifying payments or disbursing funds pursuant to the contract, or otherwise participating in carrying out the contract, to give surety bond to the United States in such amount as the Secretary may deem appropriate.

[(e)(1) No individual designated pursuant to a contract under this section as a certifying officer shall, in the absence of gross negligence or intent to defraud the United States, be liable with respect to any payments certified by him under this section.

[(2) No disbursing officer shall, in the absence of gross negligence or intent to defraud the United States, be liable with respect to any payment by him under this section if it was based upon a voucher signed by a certifying officer designated as provided in paragraph (1) of this subsection.

[(3) No such carrier shall be liable to the United States for any payments referred to in paragraph (1) or (2).

[(f) For purposes of this part, the term "carrier" means—

[(1) with respect to providers of services and other persons, a voluntary association, corporation, partnership, or other nongovernmental organization which is lawfully engaged in providing, paying for, or reimbursing the cost of, health services under group insurance policies or contracts, medical or hospital service agreements, membership or subscription contracts, or similar group arrangements, in consideration of premiums or other periodic charges payable to the carrier, including a health benefits plan duly sponsored or underwritten by an employee organization; and

[(2) with respect to providers of services only, any agency or organization (not described in paragraph (1)) with which an agreement is in effect under section 1816.]

(g) The Railroad Retirement Board shall, in accordance with such regulations as the Secretary may prescribe, contract with a [carrier or carriers] *medicare administrative contractor or contractors* to perform the functions set out in this section with respect to individuals entitled to benefits as qualified railroad retirement beneficiaries pursuant to section 226(a) of this Act and section 7(d) of the Railroad Retirement Act of 1974.

(h)(1) * * *

(2) [Each carrier having an agreement with the Secretary under subsection (a)] *The Secretary* shall maintain a toll-free telephone number or numbers at which individuals enrolled under this part may obtain the names, addresses, specialty, and telephone numbers of participating physicians and suppliers and may request a copy of an appropriate directory published under paragraph (4). [Each such carrier] *The Secretary* shall, without charge, mail a copy of such directory upon such a request.

(3)(A) In any case in which [a carrier having an agreement with the Secretary under subsection (a)] *medicare administrative contractor having a contract under section 1874A that provides for making payments under this part* is able to develop a system for the electronic transmission to [such carrier] *such contractor* of bills for services, such carrier shall establish direct lines for the electronic receipt of claims from participating physicians and suppliers.

(B) The Secretary shall establish a procedure whereby an individual enrolled under this part may assign, in an appropriate manner on the form claiming a benefit under this part for an item or service furnished by a participating physician or supplier, the individual's rights of payment under a medicare supplemental policy (described in section 1882(g)(1)) in which the individual is enrolled. In the case such an assignment is properly executed and a payment determination is made by [a carrier] *a medicare administrative contractor* with a contract under this section, [the carrier] *the contractor* shall transmit to the private entity issuing the medicare supplemental policy notice of such fact and shall include an explanation of benefits and any additional information that the Secretary may determine to be appropriate in order to enable the entity to decide whether (and the amount of) any payment is due under the policy. The Secretary may enter into agreements for the transmittal of such information to entities electronically. The Secretary shall impose user fees for the transmittal of information under this subparagraph by [a carrier] *a medicare administrative contractor*, whether electronically or otherwise, and such user fees shall be collected and retained by [the carrier] *the contractor*.

* * * * * * *

(5)(A) The Secretary shall promptly notify individuals enrolled under this part through an annual mailing of the participation program under this subsection and the publication and availability of the directories and shall make the appropriate area directory or directories available in each district and branch office of the Social Security Administration, in the offices of [carriers] *medicare administrative contractors*, and to senior citizen organizations.

(B) The annual notice provided under subparagraph (A) shall include—

(i) * * *

(iii) an explanation of the assistance offered by [carriers] *medicare administrative contractors* in obtaining the names of participating physicians and suppliers, and

* * * * * * *

(l)(1)(A) Subject to subparagraph (C), if—

(i) * * *

* * * * * * *

(iii)(I) a [carrier] *medicare administrative contractor* determines under this part or a peer review organization determines under part B of title XI that payment may not be made by reason of section 1862(a)(1) because a service otherwise covered under this title is not reasonable and necessary under the standards described in that section or (II) payment under this title for such services is denied under section 1154(a)(2) by reason of a determination under section 1154(a)(1)(B), and

* * * * * * *

(2) Each [carrier] *medicare administrative contractor* with a contract in effect under this section with respect to physicians and each peer review organization with a contract under part B of title XI shall send any notice of denial of payment for physicians' services based on section 1862(a)(1) and for which payment is not re-

quested on an assignment-related basis to the physician and the individual involved.

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(p)(1) * * *

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(3) In the case of a request for payment for an item or service furnished by a physician not submitted on an assignment-related basis and which does not include the code (or codes) required under paragraph (1)—

(A) if the physician knowingly and willfully fails to provide the code (or codes) promptly upon request of the Secretary or a [carrier] *medicare administrative contractor*, the physician may be subject to a civil money penalty in an amount not to exceed $2,000, and

* * * * * * *

(q)(1)(A) The Secretary, in consultation with groups representing physicians who furnish anesthesia services, shall establish by regulation a relative value guide for use in all [carrier] localities in making payment for physician anesthesia services furnished under this part. Such guide shall be designed so as to result in expenditures under this title for such services in an amount that would not exceed the amount of such expenditures which would otherwise occur.

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PART C—MEDICARE+CHOICE PROGRAM

ELIGIBILITY, ELECTION, AND ENROLLMENT

SEC. 1851. (a) CHOICE OF MEDICARE BENEFITS THROUGH MEDICARE+CHOICE PLANS.—

(1) * * *

(2) TYPES OF MEDICARE+CHOICE PLANS THAT MAY BE AVAILABLE.—A Medicare+Choice plan may be any of the following types of plans of health insurance:

(A) COORDINATED CARE PLANS.—Coordinated care plans which provide health care services, including but not limited to health maintenance organization plans (with or without point of service options), plans offered by provider-sponsored organizations (as defined in section 1855(d)), and preferred provider organization plans. *Specialized Medicare+Choice plans for special needs beneficiaries (as defined in section 1859(b)(4)) may be any type of coordinated care plan.*

* * * * * * *

BENEFITS AND BENEFICIARY PROTECTIONS

SEC. 1852. (a) BASIC BENEFITS.—

(1) * * *

(2) SATISFACTION OF REQUIREMENT.—

(A) * * *

* * * * * * *

(C) ELECTION OF UNIFORM COVERAGE [POLICY] *DETERMINATION*.—In the case of a Medicare+Choice organization that offers a Medicare+Choice plan in an area in which more than one local coverage [policy] *determination* is applied with respect to different parts of the area, the organization may elect to have the local coverage [policy] *determination* for the part of the area that is most beneficial to Medicare+Choice enrollees (as identified by the Secretary) apply with respect to all Medicare+Choice enrollees enrolled in the plan.

* * * * * * *

DEFINITIONS; MISCELLANEOUS PROVISIONS

SEC. 1859. (a) * * *

(b) DEFINITIONS RELATING TO MEDICARE+CHOICE PLANS.—

(1) * * *

* * * * * * *

(4) SPECIALIZED MEDICARE+CHOICE PLANS FOR SPECIAL NEEDS BENEFICIARIES.—

(A) IN GENERAL.—The term "specialized Medicare+Choice plan for special needs beneficiaries" means a Medicare+Choice plan that exclusively serves special needs beneficiaries (as defined in subparagraph (B)).

(B) SPECIAL NEEDS BENEFICIARY.—The term "special needs beneficiary" means a Medicare+Choice eligible individual who—

(i) is institutionalized (as defined by the Secretary);

(ii) is entitled to medical assistance under a State plan under title XIX; or

(iii) meets such requirements as the Secretary may determine would benefit from enrollment in such a specialized Medicare+Choice plan described in subparagraph (A) for individuals with severe or disabling chronic conditions.

* * * * * * *

(f) RESTRICTION ON ENROLLMENT FOR SPECIALIZED MEDICARE+CHOICE PLANS FOR SPECIAL NEEDS BENEFICIARIES.—In the case of a specialized Medicare+Choice plan (as defined in subsection (b)(4)), notwithstanding any other provision of this part and in accordance with regulations of the Secretary and for periods before January 1, 2008, the plan may restrict the enrollment of individuals under the plan to individuals who are within one or more classes of special needs beneficiaries.

* * * * * * *

PART D—MISCELLANEOUS PROVISIONS

DEFINITIONS OF SERVICES, INSTITUTIONS, ETC.

SEC. 1861. For purposes of this title—

Spell of Illness

(a) * * *

* * * * * * *

Supplier

(d) The term "supplier" means, unless the context otherwise requires, a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services under this title.

* * * * * * *

Hospice Care; Hospice Program

(dd)(1) * * *

* * * * * * *

(5)(A) * * *

* * * * * * *

(D) In extraordinary, exigent, or other non-routine circumstances, such as unanticipated periods of high patient loads, staffing shortages due to illness or other events, or temporary travel of a patient outside a hospice program's service area, a hospice program may enter into arrangements with another hospice program for the provision by that other program of services described in paragraph (2)(A)(ii)(I). The provisions of paragraph (2)(A)(ii)(II) shall apply with respect to the services provided under such arrangements.

(E) A hospice program may provide services described in paragraph (1)(A) other than directly by the program if the services are highly specialized services of a registered professional nurse and are provided non-routinely and so infrequently so that the provision of such services directly would be impracticable and prohibitively expensive.

* * * * * * *

Discharge Planning Process

(ee)(1) * * *

(2) The Secretary shall develop guidelines and standards for the discharge planning process in order to ensure a timely and smooth transition to the most appropriate type of and setting for post-hospital or rehabilitative care. The guidelines and standards shall include the following:

(A) * * *

* * * * * * *

(D) A discharge planning evaluation must include an evaluation of a patient's likely need for appropriate post-hospital services, including [hospice services] *hospice care and post-hospital extended care services*, and the availability of those services, including the availability of home health services through individuals and entities that participate in the program under this title and that serve the area in which the patient resides and that request to be listed by the hospital as available *and, in the case of individuals who are likely to need*

post-hospital extended care services, the availability of such services through facilities that participate in the program under this title and that serve the area in which the patient resides.

* * * * * * *

EXCLUSIONS FROM COVERAGE AND MEDICARE AS SECONDARY PAYER

SEC. 1862. (a) Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services—

(1) * * *

* * * * * * *

Paragraph (7) shall not apply to Federally qualified health center services described in section 1861(aa)(3)(B). In making a national coverage determination (as defined in paragraph (1)(B) of section 1869(f)) the Secretary shall ensure that the public is afforded notice and opportunity to comment prior to implementation by the Secretary of the determination; meetings of advisory committees **[**established under section 1114(f)**]** with respect to the determination are made on the record; in making the determination, the Secretary has considered applicable information (including clinical experience and medical, technical, and scientific evidence) with respect to the subject matter of the determination; and in the determination, provide a clear statement of the basis for the determination (including responses to comments received from the public), the assumptions underlying that basis, and make available to the public the data (other than proprietary data) considered in making the determination.

* * * * * * *

(d) For purposes of subsection (a)(1)(A), in the case of any item or service that is required to be provided pursuant to section 1867 to an individual who is entitled to benefits under this title, determinations as to whether the item or service is reasonable and necessary shall be made on the basis of the information available to the treating physician or practitioner (including the patient's presenting symptoms or complaint) at the time the item or service was ordered or furnished by the physician or practitioner (and not on the patient's principal diagnosis). When making such determinations with respect to such an item or service, the Secretary shall not consider the frequency with which the item or service was provided to the patient before or after the time of the admission or visit.

* * * * * * *

[(i)**]** *(j)*(1) Any advisory committee appointed **[**under subsection (f)**]** to advise the Secretary on matters relating to the interpretation, application, or implementation of **[**section 1862(a)(1)**]** *subsection (a)(1)* shall assure the full participation of a nonvoting member in the deliberations of the advisory committee, and shall provide such nonvoting member access to all information and data made available to voting members of the advisory committee, other than information that—

(A) is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section (relating to trade secrets); or

(B) the Secretary determines would present a conflict of interest relating to such nonvoting member.

(2) If an advisory committee described in paragraph (1) organizes into panels of experts according to types of items or services considered by the advisory committee, any such panel of experts may report any recommendation with respect to such items or services directly to the Secretary without the prior approval of the advisory committee or an executive committee thereof.

(k)(1) Subject to paragraph (2), a group health plan (as defined in subsection (a)(1)(A)(v)) providing supplemental or secondary coverage to individuals also entitled to services under this title shall not require a medicare claims determination under this title for dental benefits specifically excluded under subsection (a)(12) as a condition of making a claims determination for such benefits under the group health plan.

(2) A group health plan may require a claims determination under this title in cases involving or appearing to involve inpatient dental hospital services or dental services expressly covered under this title pursuant to actions taken by the Secretary.

* * * * * * *

[AGREEMENTS WITH PROVIDERS OF SERVICES**]**

AGREEMENTS WITH PROVIDERS OF SERVICES; ENROLLMENT PROCESSES

SEC. 1866. (a)(1) Any provider of services (except a fund designated for purposes of section 1814(g) and section 1835(e)) shall be qualified to participate under this title and shall be eligible for payments under this title if it files with the Secretary an agreement—

(A) * * *

* * * * * * *

(R) to contract only with a health care clearinghouse (as defined in section 1171) that meets each standard and implementation specification adopted or established under part C of title XI on or after the date on which the health care clearinghouse is required to comply with the standard or specification, **[**and**]**

(S) in the case of a hospital that has a financial interest (as specified by the Secretary in regulations) in an entity to which individuals are referred as described in section 1861(ee)(2)(H)(ii), or in which such an entity has such a financial interest, or in which another entity has such a financial interest (directly or indirectly) with such hospital and such an entity, to maintain and disclose to the Secretary (in a form and manner specified by the Secretary) information on—

(i) * * *

* * * * * * *

(iii) the percentage of such individuals who received such services from such provider (or another such provider)**[**.**]**, *and*

(T) in the case of hospitals that are not otherwise subject to the Occupational Safety and Health Act of 1970 or a State occupational safety and health plan that is approved under section 18(b) of such Act, to comply with the Bloodborne Pathogens

standard under section 1910.1030 of title 29 of the Code of Federal Regulations (or as subsequently redesignated).

* * * * * * *

(b)(1) * * *

* * * * * * *

(4)(A) A hospital that fails to comply with the requirement of subsection (a)(1)(T) (relating to the Bloodborne Pathogens standard) is subject to a civil money penalty in an amount described in subparagraph (B), but is not subject to termination of an agreement under this section.

(B) The amount referred to in subparagraph (A) is an amount that is similar to the amount of civil penalties that may be imposed under section 17 of the Occupational Safety and Health Act of 1970 for a violation of the Bloodborne Pathogens standard referred to in subsection (a)(1)(T) by a hospital that is subject to the provisions of such Act.

(C) A civil money penalty under this paragraph shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A are imposed and collected under that section.

* * * * * * *

(h)(1)*(A)* Except as provided in paragraph (2), an institution or agency dissatisfied with a determination by the Secretary that it is not a provider of services or with a determination described in subsection (b)(2) shall be entitled to a hearing thereon by the Secretary (after reasonable notice) to the same extent as is provided in section 205(b), and to judicial review of the Secretary's final decision after such hearing as is provided in section 205(g), except that, in so applying such sections and in applying section 205(l) thereto, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

(B) An institution or agency described in subparagraph (A) that has filed for a hearing under subparagraph (A) shall have expedited access to judicial review under this subparagraph in the same manner as providers of services, suppliers, and individuals entitled to benefits under part A or enrolled under part B, or both, may obtain expedited access to judicial review under the process established under section 1869(b)(2). Nothing in this subparagraph shall be construed to affect the application of any remedy imposed under section 1819 during the pendency of an appeal under this subparagraph.

* * * * * * *

(j) ENROLLMENT PROCESS FOR PROVIDERS OF SERVICES AND SUPPLIERS.—

(1) ENROLLMENT PROCESS.—

(A) IN GENERAL.—The Secretary shall establish by regulation a process for the enrollment of providers of services and suppliers under this title.

(B) DEADLINES.—The Secretary shall establish by regulation procedures under which there are deadlines for actions on applications for enrollment (and, if applicable, renewal

of enrollment). The Secretary shall monitor the performance of medicare administrative contractors in meeting the deadlines established under this subparagraph.

(C) CONSULTATION BEFORE CHANGING PROVIDER ENROLLMENT FORMS.—The Secretary shall consult with providers of services and suppliers before making changes in the provider enrollment forms required of such providers and suppliers to be eligible to submit claims for which payment may be made under this title.

(2) HEARING RIGHTS IN CASES OF DENIAL OR NON-RENEWAL.—A provider of services or supplier whose application to enroll (or, if applicable, to renew enrollment) under this title is denied may have a hearing and judicial review of such denial under the procedures that apply under subsection (h)(1)(A) to a provider of services that is dissatisfied with a determination by the Secretary.

* * * * * * *

EXAMINATION AND TREATMENT FOR EMERGENCY MEDICAL CONDITIONS AND WOMEN IN LABOR

SEC. 1867. (a) * * *

* * * * * * *

(d) ENFORCEMENT.—

(1) * * *

* * * * * * *

(3) CONSULTATION WITH PEER REVIEW ORGANIZATIONS.—In considering allegations of violations of the requirements of this section in imposing sanctions under paragraph (1) *or in terminating a hospital's participation under this title*, the Secretary shall request the appropriate utilization and quality control peer review organization (with a contract under part B of title XI) to assess whether the individual involved had an emergency medical condition which had not been stabilized, and provide a report on its findings. Except in the case in which a delay would jeopardize the health or safety of individuals, the Secretary shall request such a review before effecting a sanction under paragraph (1) and shall provide a period of at least 60 days for such review. *Except in the case in which a delay would jeopardize the health or safety of individuals, the Secretary shall also request such a review before making a compliance determination as part of the process of terminating a hospital's participation under this title for violations related to the appropriateness of a medical screening examination, stabilizing treatment, or an appropriate transfer as required by this section, and shall provide a period of 5 days for such review. The Secretary shall provide a copy of the organization's report to the hospital or physician consistent with confidentiality requirements imposed on the organization under such part B.*

(4) NOTICE UPON CLOSING AN INVESTIGATION.—The Secretary shall establish a procedure to notify hospitals and physicians when an investigation under this section is closed.

* * * * * * *

[PRACTICING PHYSICIANS ADVISORY COUNCIL]

PRACTICING PHYSICIANS ADVISORY COUNCIL; MEDICARE PROVIDER OMBUDSMAN

SEC. 1868. (a) *PRACTICING PHYSICIANS ADVISORY COUNCIL.—(1)* The Secretary shall appoint, based upon nominations submitted by medical organizations representing physicians, a Practicing Physicians Advisory Council (in this [section] *subsection* referred to as the "Council") to be composed of 15 physicians, each of whom has submitted at least 250 claims for physicians' services under this title in the previous year. At least 11 of the members of the Council shall be physicians described in section 1861(r)(1) and the members of the Council shall include both participating and nonparticipating physicians and physicians practicing in rural areas and underserved urban areas.

[(b)] *(2)* The Council shall meet once during each calendar quarter to discuss certain proposed changes in regulations and carrier manual instructions related to physician services identified by the Secretary. To the extent feasible and consistent with statutory deadlines, such consultation shall occur before the publication of such proposed changes.

[(c)] *(3)* Members of the Council shall be entitled to receive reimbursement of expenses and per diem in lieu of subsistence in the same manner as other members of advisory councils appointed by the Secretary are provided such reimbursement and per diem under this title.

(b) MEDICARE PROVIDER OMBUDSMAN.—The Secretary shall appoint within the Department of Health and Human Services a Medicare Provider Ombudsman. The Ombudsman shall—

(1) provide assistance, on a confidential basis, to providers of services and suppliers with respect to complaints, grievances, and requests for information concerning the programs under this title (including provisions of title XI insofar as they relate to this title and are not administered by the Office of the Inspector General of the Department of Health and Human Services) and in the resolution of unclear or conflicting guidance given by the Secretary and medicare contractors to such providers of services and suppliers regarding such programs and provisions and requirements under this title and such provisions; and

(2) submit recommendations to the Secretary for improvement in the administration of this title and such provisions, including—

(A) recommendations to respond to recurring patterns of confusion in this title and such provisions (including recommendations regarding suspending imposition of sanctions where there is widespread confusion in program administration), and

(B) recommendations to provide for an appropriate and consistent response (including not providing for audits) in cases of self-identified overpayments by providers of services and suppliers.

The Ombudsman shall not serve as an advocate for any increases in payments or new coverage of services, but may identify issues and problems in payment or coverage policies.

(c) COUNCIL FOR TECHNOLOGY AND INNOVATION.—

(1) ESTABLISHMENT.—The Secretary shall establish a Council for Technology and Innovation within the Centers for Medicare & Medicaid Services (in this section referred to as "CMS").

(2) COMPOSITION.—The Council shall be composed of senior CMS staff and clinicians and shall be chaired by the Executive Coordinator for Technology and Innovation (appointed or designated under paragraph (4)).

(3) DUTIES.—The Council shall coordinate the activities of coverage, coding, and payment processes under this title with respect to new technologies and procedures, including new drug therapies, and shall coordinate the exchange of information on new technologies between CMS and other entities that make similar decisions.

(4) EXECUTIVE COORDINATOR FOR TECHNOLOGY AND INNOVATION.—The Secretary shall appoint (or designate) a noncareer appointee (as defined in section 3132(a)(7) of title 5, United States Code) who shall serve as the Executive Coordinator for Technology and Innovation. Such executive coordinator shall report to the Administrator of CMS, shall chair the Council, shall oversee the execution of its duties, and shall serve as a single point of contact for outside groups and entities regarding the coverage, coding, and payment processes under this title.

DETERMINATIONS; APPEALS

SEC. 1869. (a) INITIAL DETERMINATIONS.—

(1) * * *

* * * * * * *

(4) REQUIREMENTS OF NOTICE OF DETERMINATIONS.—With respect to an initial determination insofar as it results in a denial of a claim for benefits—

(A) the written notice on the determination shall include—

(i) the reasons for the determination, including whether a local medical review policy or a local coverage determination was used;

(ii) the procedures for obtaining additional information concerning the determination, including the information described in subparagraph (B); and

(iii) notification of the right to seek a redetermination or otherwise appeal the determination and instructions on how to initiate such a redetermination under this section; and

(B) the person provided such notice may obtain, upon request, the specific provision of the policy, manual, or regulation used in making the determination.

(5) REQUIREMENTS OF NOTICE OF REDETERMINATIONS.—With respect to a redetermination insofar as it results in a denial of a claim for benefits—

(A) the written notice on the redetermination shall include—

(i) the specific reasons for the redetermination;

(ii) as appropriate, a summary of the clinical or scientific evidence used in making the redetermination;

(iii) a description of the procedures for obtaining additional information concerning the redetermination; and

(iv) notification of the right to appeal the redetermination and instructions on how to initiate such an appeal under this section;

(B) such written notice shall be provided in printed form and written in a manner calculated to be understood by the individual entitled to benefits under part A or enrolled under part B, or both; and

(C) the person provided such notice may obtain, upon request, information on the specific provision of the policy, manual, or regulation used in making the redetermination.

(b) APPEAL RIGHTS.—

(1) IN GENERAL.—

(A) RECONSIDERATION OF INITIAL DETERMINATION.—Subject to subparagraph (D), any individual dissatisfied with any initial determination under subsection (a)(1) shall be entitled to reconsideration of the determination, and, subject to subparagraphs (D) and (E), a hearing thereon by the Secretary to the same extent as is provided in section 205(b) and*, subject to paragraph (2),* to judicial review of the Secretary's final decision after such hearing as is provided in section 205(g). For purposes of the preceding sentence, any reference to the "Commissioner of Social Security" or the "Social Security Administration" in subsection (g) or (l) of section 205 shall be considered a reference to the "Secretary" or the "Department of Health and Human Services", respectively.

* * * * * * *

(F) EXPEDITED [PROCEEDINGS.—

[(i) EXPEDITED DETERMINATION] *DETERMINATIONS AND RECONSIDERATIONS*.—In the case of an individual who has received notice from a provider of services that such provider plans—

[(I)] *(i)* to terminate services provided to an individual and a physician certifies that failure to continue the provision of such services is likely to place the individual's health at significant risk, or

[(II)] *(ii)* to discharge the individual from the provider of services,

the individual may request, in writing or orally, an expedited determination or an expedited reconsideration of an initial determination made under subsection (a)(1), as the case may be, and the Secretary shall provide such expedited determination or expedited reconsideration.

[(ii) EXPEDITED HEARING.—In a hearing by the Secretary under this section, in which the moving party alleges that no material issues of fact are in dispute, the Secretary shall make an expedited determination as to whether any such facts are in dispute and, if not, shall render a decision expeditiously.]

* * * * * * *

(2) EXPEDITED ACCESS TO JUDICIAL REVIEW.—

(A) IN GENERAL.—The Secretary shall establish a process under which a provider of services or supplier that furnishes an item or service or an individual entitled to benefits under part A or enrolled under part B, or both, who has filed an appeal under paragraph (1) may obtain access to judicial review when a review panel (described in subparagraph (D)), on its own motion or at the request of the appellant, determines that no entity in the administrative appeals process has the authority to decide the question of law or regulation relevant to the matters in controversy and that there is no material issue of fact in dispute. The appellant may make such request only once with respect to a question of law or regulation in a case of an appeal.

(B) PROMPT DETERMINATIONS.—If, after or coincident with appropriately filing a request for an administrative hearing, the appellant requests a determination by the appropriate review panel that no review panel has the authority to decide the question of law or regulations relevant to the matters in controversy and that there is no material issue of fact in dispute and if such request is accompanied by the documents and materials as the appropriate review panel shall require for purposes of making such determination, such review panel shall make a determination on the request in writing within 60 days after the date such review panel receives the request and such accompanying documents and materials. Such a determination by such review panel shall be considered a final decision and not subject to review by the Secretary.

(C) ACCESS TO JUDICIAL REVIEW.—

(i) IN GENERAL.—If the appropriate review panel—

(I) determines that there are no material issues of fact in dispute and that the only issue is one of law or regulation that no review panel has the authority to decide; or

(II) fails to make such determination within the period provided under subparagraph (B);

then the appellant may bring a civil action as described in this subparagraph.

(ii) DEADLINE FOR FILING.—Such action shall be filed, in the case described in—

(I) clause (i)(I), within 60 days of date of the determination described in such subparagraph; or

(II) clause (i)(II), within 60 days of the end of the period provided under subparagraph (B) for the determination.

(iii) VENUE.—Such action shall be brought in the district court of the United States for the judicial district in which the appellant is located (or, in the case of an action brought jointly by more than one applicant, the judicial district in which the greatest number of applicants are located) or in the district court for the District of Columbia.

(iv) INTEREST ON AMOUNTS IN CONTROVERSY.—Where a provider of services or supplier seeks judicial review

pursuant to this paragraph, the amount in controversy shall be subject to annual interest beginning on the first day of the first month beginning after the 60-day period as determined pursuant to clause (ii) and equal to the rate of interest on obligations issued for purchase by the Federal Hospital Insurance Trust Fund and by the Federal Supplementary Medical Insurance Trust Fund for the month in which the civil action authorized under this paragraph is commenced, to be awarded by the reviewing court in favor of the prevailing party. No interest awarded pursuant to the preceding sentence shall be deemed income or cost for the purposes of determining reimbursement due providers of services or suppliers under this Act.

(D) REVIEW PANELS.—For purposes of this subsection, a "review panel" is a panel consisting of 3 members (who shall be administrative law judges, members of the Departmental Appeals Board, or qualified individuals associated with a qualified independent contractor (as defined in subsection (c)(2)) or with another independent entity) designated by the Secretary for purposes of making determinations under this paragraph.

(3) REQUIRING FULL AND EARLY PRESENTATION OF EVIDENCE BY PROVIDERS.—A provider of services or supplier may not introduce evidence in any appeal under this section that was not presented at the reconsideration conducted by the qualified independent contractor under subsection (c), unless there is good cause which precluded the introduction of such evidence at or before that reconsideration.

* * * * * * *

(c) CONDUCT OF RECONSIDERATIONS BY INDEPENDENT CONTRACTORS.—

(1) * * *

* * * * * * *

(3) REQUIREMENTS.—Any qualified independent contractor entering into a contract with the Secretary under this subsection shall meet all of the following requirements:

(A) IN GENERAL.—The qualified independent contractor shall perform such duties and functions and assume such responsibilities as may be required by the Secretary to carry out the provisions of this subsection, and shall have **[**sufficient training and expertise in medical science and legal matters**]** *sufficient medical, legal, and other expertise (including knowledge of the program under this title) and sufficient staffing* to make reconsiderations under this subsection.

(B) RECONSIDERATIONS.—

(i) IN GENERAL.—The qualified independent contractor shall review initial determinations. Where an initial determination is made with respect to whether an item or service is reasonable and necessary for the diagnosis or treatment of illness or injury (under section 1862(a)(1)(A)), such review shall include consideration of the facts and circumstances of the initial de-

termination by a panel of physicians or other appropriate health care professionals and any decisions with respect to the reconsideration shall be based on applicable information, including clinical experience *(including the medical records of the individual involved)* and medical, technical, and scientific evidence.

* * * * * * *

[(D) LIMITATION ON INDIVIDUAL REVIEWING DETERMINATIONS.—

[(i) PHYSICIANS AND HEALTH CARE PROFESSIONAL.—No physician or health care professional under the employ of a qualified independent contractor may review—

[(I) determinations regarding health care services furnished to a patient if the physician or health care professional was directly responsible for furnishing such services; or

[(II) determinations regarding health care services provided in or by an institution, organization, or agency, if the physician or any member of the family of the physician or health care professional has, directly or indirectly, a significant financial interest in such institution, organization, or agency.

[(ii) FAMILY DESCRIBED.—For purposes of this paragraph, the family of a physician or health care professional includes the spouse (other than a spouse who is legally separated from the physician or health care professional under a decree of divorce or separate maintenance), children (including stepchildren and legally adopted children), grandchildren, parents, and grandparents of the physician or health care professional.]

(D) QUALIFICATIONS FOR REVIEWERS.—The requirements of subsection (g) shall be met (relating to qualifications of reviewing professionals).

(E) EXPLANATION OF DECISION.—Any decision with respect to a reconsideration of a qualified independent contractor shall be in writing, *be written in a manner calculated to be understood by the individual entitled to benefits under part A or enrolled under part B, or both, and shall include (to the extent appropriate)* and shall include a detailed explanation of the decision as well as a discussion of the pertinent facts and applicable regulations applied in making such decision, *and a notification of the right to appeal such determination and instructions on how to initiate such appeal under this section* and in the case of a determination of whether an item or service is reasonable and necessary for the diagnosis or treatment of illness or injury (under section 1862(a)(1)(A)) an explanation of the medical and scientific rationale for the decision.

* * * * * * *

(I) DATA COLLECTION.—

(i) * * *

(ii) TYPE OF DATA COLLECTED.—Each qualified independent contractor shall keep accurate records of each decision made, consistent with standards established by the Secretary for such purpose. Such records shall be maintained in an electronic database in a manner that provides for identification of the following:

(I) * * *

* * * * * * *

(III) Situations suggesting the need for changes in national or local coverage [policy] *determination*.

(IV) Situations suggesting the need for changes in local [medical review policies] *coverage determinations*.

* * * * * * *

(J) HEARINGS BY THE SECRETARY.—The qualified independent contractor shall (i) [prepare] *submit* such information as is required for an appeal of a decision of the contractor [with respect to a reconsideration to the Secretary for a hearing, including as necessary, explanations of issues involved in the decision and relevant policies], and (ii) participate in such hearings as required by the Secretary.

(K) INDEPENDENCE REQUIREMENTS.—

(i) IN GENERAL.—Subject to clause (ii), a qualified independent contractor shall not conduct any activities in a case unless the entity—

(I) is not a related party (as defined in subsection (g)(5));

(II) does not have a material familial, financial, or professional relationship with such a party in relation to such case; and

(III) does not otherwise have a conflict of interest with such a party.

(ii) EXCEPTION FOR REASONABLE COMPENSATION.—Nothing in clause (i) shall be construed to prohibit receipt by a qualified independent contractor of compensation from the Secretary for the conduct of activities under this section if the compensation is provided consistent with clause (iii).

(iii) LIMITATIONS ON ENTITY COMPENSATION.—Compensation provided by the Secretary to a qualified independent contractor in connection with reviews under this section shall not be contingent on any decision rendered by the contractor or by any reviewing professional.

(4) NUMBER OF QUALIFIED INDEPENDENT CONTRACTORS.—The Secretary shall enter into contracts with [not fewer than 12 qualified independent contractors under this subsection] *a sufficient number of qualified independent contractors (but not fewer than 4 such contractors) to conduct reconsiderations consistent with the timeframes applicable under this subsection*.

* * * * * * *

(d) DEADLINES FOR HEARINGS BY THE SECRETARY; *NOTICE*.—
(1) * * *

* * * * * * *

(4) NOTICE.—Notice of the decision of an administrative law judge shall be in writing in a manner calculated to be understood by the individual entitled to benefits under part A or enrolled under part B, or both, and shall include—

(A) the specific reasons for the determination (including, to the extent appropriate, a summary of the clinical or scientific evidence used in making the determination);

(B) the procedures for obtaining additional information concerning the decision; and

(C) notification of the right to appeal the decision and instructions on how to initiate such an appeal under this section.

* * * * * * *

(f) REVIEW OF COVERAGE DETERMINATIONS.—
(1) * * *
(2) LOCAL COVERAGE DETERMINATION.—
(A) IN GENERAL.—Review of any local coverage determination shall be subject to the following limitations:
(i) Upon the filing of a complaint by an aggrieved party, such a determination shall be reviewed by an administrative law judge [of the Social Security Administration]. The administrative law judge—
(I) * * *

* * * * * * *

(4) PENDING NATIONAL COVERAGE DETERMINATIONS.—
(A) IN GENERAL.—In the event the Secretary has not issued a national coverage or noncoverage determination with respect to a particular type or class of items or services, an aggrieved person (as described in paragraph (5)) may submit to the Secretary a request to make such a determination with respect to such items or services. By not later than the end of the 90-day period beginning on the date the Secretary receives such a request (notwithstanding the receipt by the Secretary of new evidence (if any) during such 90-day period), the Secretary shall take one of the following actions:
(i) * * *

* * * * * * *

(iv) Issue a notice that states that the Secretary has not completed a review of the request for a national coverage determination and that includes an identification of the remaining steps in the Secretary's review process and a deadline by which the Secretary will complete the review and take an action described in [subclause (I), (II), or (III)] *clause (i), (ii), or (iii)*.

(B) DEEMED ACTION BY THE SECRETARY.—In the case of an action described in [clause (i)(IV)] *subparagraph (A)(iv)*, if the Secretary fails to take an action referred to in such clause by the deadline specified by the Secretary under such clause, then the Secretary is deemed to have

taken an action described in [clause (i)(III)] *subparagraph (A)(iii)* as of the deadline.

(C) EXPLANATION OF DETERMINATION.—When issuing a determination under [clause (i)] *subparagraph (A)*, the Secretary shall include an explanation of the basis for the determination. An action taken under clause (i) (other than [subclause (IV)] *clause (iv)*) is deemed to be a national coverage determination for purposes of review under [subparagraph (A)] *paragraph (1)(A)*.

* * * * * * *

(g) QUALIFICATIONS OF REVIEWERS.—

(1) IN GENERAL.—In reviewing determinations under this section, a qualified independent contractor shall assure that—

(A) each individual conducting a review shall meet the qualifications of paragraph (2);

(B) compensation provided by the contractor to each such reviewer is consistent with paragraph (3); and

(C) in the case of a review by a panel described in subsection (c)(3)(B) composed of physicians or other health care professionals (each in this subsection referred to as a "reviewing professional"), a reviewing professional meets the qualifications described in paragraph (4) and, where a claim is regarding the furnishing of treatment by a physician (allopathic or osteopathic) or the provision of items or services by a physician (allopathic or osteopathic), a reviewing professional shall be a physician (allopathic or osteopathic).

(2) INDEPENDENCE.—

(A) IN GENERAL.—Subject to subparagraph (B), each individual conducting a review in a case shall—

(i) not be a related party (as defined in paragraph (5));

(ii) not have a material familial, financial, or professional relationship with such a party in the case under review; and

(iii) not otherwise have a conflict of interest with such a party.

(B) EXCEPTION.—Nothing in subparagraph (A) shall be construed to—

(i) prohibit an individual, solely on the basis of a participation agreement with a fiscal intermediary, carrier, or other contractor, from serving as a reviewing professional if—

(I) the individual is not involved in the provision of items or services in the case under review;

(II) the fact of such an agreement is disclosed to the Secretary and the individual entitled to benefits under part A or enrolled under part B, or both, (or authorized representative) and neither party objects; and

(III) the individual is not an employee of the intermediary, carrier, or contractor and does not provide services exclusively or primarily to or on behalf of such intermediary, carrier, or contractor;

(ii) prohibit an individual who has staff privileges at the institution where the treatment involved takes place from serving as a reviewer merely on the basis of having such staff privileges if the existence of such privileges is disclosed to the Secretary and such individual (or authorized representative), and neither party objects; or

(iii) prohibit receipt of compensation by a reviewing professional from a contractor if the compensation is provided consistent with paragraph (3).

For purposes of this paragraph, the term "participation agreement" means an agreement relating to the provision of health care services by the individual and does not include the provision of services as a reviewer under this subsection.

(3) LIMITATIONS ON REVIEWER COMPENSATION.—Compensation provided by a qualified independent contractor to a reviewer in connection with a review under this section shall not be contingent on the decision rendered by the reviewer.

(4) LICENSURE AND EXPERTISE.—Each reviewing professional shall be—

(A) a physician (allopathic or osteopathic) who is appropriately credentialed or licensed in one or more States to deliver health care services and has medical expertise in the field of practice that is appropriate for the items or services at issue; or

(B) a health care professional who is legally authorized in one or more States (in accordance with State law or the State regulatory mechanism provided by State law) to furnish the health care items or services at issue and has medical expertise in the field of practice that is appropriate for such items or services.

(5) RELATED PARTY DEFINED.—For purposes of this section, the term "related party" means, with respect to a case under this title involving a specific individual entitled to benefits under part A or enrolled under part B, or both, any of the following:

(A) The Secretary, the medicare administrative contractor involved, or any fiduciary, officer, director, or employee of the Department of Health and Human Services, or of such contractor.

(B) The individual (or authorized representative).

(C) The health care professional that provides the items or services involved in the case.

(D) The institution at which the items or services (or treatment) involved in the case are provided.

(E) The manufacturer of any drug or other item that is included in the items or services involved in the case.

(F) Any other party determined under any regulations to have a substantial interest in the case involved.

(h) PRIOR DETERMINATION PROCESS FOR CERTAIN ITEMS AND SERVICES.—

(1) ESTABLISHMENT OF PROCESS.—

(A) IN GENERAL.—With respect to a medicare administrative contractor that has a contract under section 1874A that

provides for making payments under this title with respect to eligible items and services described in subparagraph (C), the Secretary shall establish a prior determination process that meets the requirements of this subsection and that shall be applied by such contractor in the case of eligible requesters.

(B) ELIGIBLE REQUESTER.—For purposes of this subsection, each of the following shall be an eligible requester:

(i) A physician, but only with respect to eligible items and services for which the physician may be paid directly.

(ii) An individual entitled to benefits under this title, but only with respect to an item or service for which the individual receives, from the physician who may be paid directly for the item or service, an advance beneficiary notice under section 1879(a) that payment may not be made (or may no longer be made) for the item or service under this title.

(C) ELIGIBLE ITEMS AND SERVICES.—For purposes of this subsection and subject to paragraph (2), eligible items and services are items and services which are physicians' services (as defined in paragraph (4)(A) of section 1848(f) for purposes of calculating the sustainable growth rate under such section).

(2) SECRETARIAL FLEXIBILITY.—The Secretary shall establish by regulation reasonable limits on the categories of eligible items and services for which a prior determination of coverage may be requested under this subsection. In establishing such limits, the Secretary may consider the dollar amount involved with respect to the item or service, administrative costs and burdens, and other relevant factors.

(3) REQUEST FOR PRIOR DETERMINATION.—

(A) IN GENERAL.—Subject to paragraph (2), under the process established under this subsection an eligible requester may submit to the contractor a request for a determination, before the furnishing of an eligible item or service involved as to whether the item or service is covered under this title consistent with the applicable requirements of section 1862(a)(1)(A) (relating to medical necessity).

(B) ACCOMPANYING DOCUMENTATION.—The Secretary may require that the request be accompanied by a description of the item or service, supporting documentation relating to the medical necessity for the item or service, and any other appropriate documentation. In the case of a request submitted by an eligible requester who is described in paragraph (1)(B)(ii), the Secretary may require that the request also be accompanied by a copy of the advance beneficiary notice involved.

(4) RESPONSE TO REQUEST.—

(A) IN GENERAL.—Under such process, the contractor shall provide the eligible requester with written notice of a determination as to whether—

(i) the item or service is so covered;

(ii) the item or service is not so covered; or

(iii) the contractor lacks sufficient information to make a coverage determination.

If the contractor makes the determination described in clause (iii), the contractor shall include in the notice a description of the additional information required to make the coverage determination.

(B) DEADLINE TO RESPOND.—Such notice shall be provided within the same time period as the time period applicable to the contractor providing notice of initial determinations on a claim for benefits under subsection (a)(2)(A).

(C) INFORMING BENEFICIARY IN CASE OF PHYSICIAN REQUEST.—In the case of a request in which an eligible requester is not the individual described in paragraph (1)(B)(ii), the process shall provide that the individual to whom the item or service is proposed to be furnished shall be informed of any determination described in clause (ii) (relating to a determination of non-coverage) and the right (referred to in paragraph (6)(B)) to obtain the item or service and have a claim submitted for the item or service.

(5) EFFECT OF DETERMINATIONS.—

(A) BINDING NATURE OF POSITIVE DETERMINATION.—If the contractor makes the determination described in paragraph (4)(A)(i), such determination shall be binding on the contractor in the absence of fraud or evidence of misrepresentation of facts presented to the contractor.

(B) NOTICE AND RIGHT TO REDETERMINATION IN CASE OF A DENIAL.—

(i) IN GENERAL.—If the contractor makes the determination described in paragraph (4)(A)(ii)—

(I) the eligible requester has the right to a redetermination by the contractor on the determination that the item or service is not so covered; and

(II) the contractor shall include in notice under paragraph (4)(A) a brief explanation of the basis for the determination, including on what national or local coverage or noncoverage determination (if any) the determination is based, and the right to such a redetermination.

(ii) DEADLINE FOR REDETERMINATIONS.—The contractor shall complete and provide notice of such redetermination within the same time period as the time period applicable to the contractor providing notice of redeterminations relating to a claim for benefits under subsection (a)(3)(C)(ii).

(6) LIMITATION ON FURTHER REVIEW.—

(A) IN GENERAL.—Contractor determinations described in paragraph (4)(A)(ii) or (4)(A)(iii) (and redeterminations made under paragraph (5)(B)), relating to pre-service claims are not subject to further administrative appeal or judicial review under this section or otherwise.

(B) DECISION NOT TO SEEK PRIOR DETERMINATION OR NEGATIVE DETERMINATION DOES NOT IMPACT RIGHT TO OBTAIN SERVICES, SEEK REIMBURSEMENT, OR APPEAL RIGHTS.—Nothing in this subsection shall be construed as affecting the right of an individual who—

(i) decides not to seek a prior determination under this subsection with respect to items or services; or

(ii) seeks such a determination and has received a determination described in paragraph (4)(A)(ii),

from receiving (and submitting a claim for) such items services and from obtaining administrative or judicial review respecting such claim under the other applicable provisions of this section. Failure to seek a prior determination under this subsection with respect to items and services shall not be taken into account in such administrative or judicial review.

(C) NO PRIOR DETERMINATION AFTER RECEIPT OF SERVICES.—Once an individual is provided items and services, there shall be no prior determination under this subsection with respect to such items or services.

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REGULATIONS

SEC. 1871. (a)(1) * * *

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(3) If the Secretary publishes a final regulation that includes a provision that is not a logical outgrowth of a previously published notice of proposed rulemaking or interim final rule, such provision shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation.

* * * * * * *

(d)(1)(A) A substantive change in regulations, manual instructions, interpretative rules, statements of policy, or guidelines of general applicability under this title shall not be applied (by extrapolation or otherwise) retroactively to items and services furnished before the effective date of the change, unless the Secretary determines that—

(i) such retroactive application is necessary to comply with statutory requirements; or

(ii) failure to apply the change retroactively would be contrary to the public interest.

(B)(i) Except as provided in clause (ii), a substantive change referred to in subparagraph (A) shall not become effective before the end of the 30-day period that begins on the date that the Secretary has issued or published, as the case may be, the substantive change.

(ii) The Secretary may provide for such a substantive change to take effect on a date that precedes the end of the 30-day period under clause (i) if the Secretary finds that waiver of such 30-day period is necessary to comply with statutory requirements or that the application of such 30-day period is contrary to the public interest. If the Secretary provides for an earlier effective date pursuant to this clause, the Secretary shall include in the issuance or publication of the substantive change a finding described in the first sentence, and a brief statement of the reasons for such finding.

(C) No action shall be taken against a provider of services or supplier with respect to noncompliance with such a substantive change

for items and services furnished before the effective date of such a change.

(2)(A) If—

(i) a provider of services or supplier follows the written guidance (which may be transmitted electronically) provided by the Secretary or by a medicare contractor (as defined in section 1889(g)) acting within the scope of the contractor's contract authority, with respect to the furnishing of items or services and submission of a claim for benefits for such items or services with respect to such provider or supplier;

(ii) the Secretary determines that the provider of services or supplier has accurately presented the circumstances relating to such items, services, and claim to the contractor in writing; and

(iii) the guidance was in error;

the provider of services or supplier shall not be subject to any sanction (including any penalty or requirement for repayment of any amount) if the provider of services or supplier reasonably relied on such guidance.

(B) Subparagraph (A) shall not be construed as preventing the recoupment or repayment (without any additional penalty) relating to an overpayment insofar as the overpayment was solely the result of a clerical or technical operational error.

(e)(1) Not later than 2 years after the date of the enactment of this subsection, and every 2 years thereafter, the Secretary shall submit to Congress a report with respect to the administration of this title and areas of inconsistency or conflict among the various provisions under law and regulation.

(2) In preparing a report under paragraph (1), the Secretary shall collect—

(A) information from individuals entitled to benefits under part A or enrolled under part B, or both, providers of services, and suppliers and from the Medicare Beneficiary Ombudsman and the Medicare Provider Ombudsman with respect to such areas of inconsistency and conflict; and

(B) information from medicare contractors that tracks the nature of written and telephone inquiries.

(3) A report under paragraph (1) shall include a description of efforts by the Secretary to reduce such inconsistency or conflicts, and recommendations for legislation or administrative action that the Secretary determines appropriate to further reduce such inconsistency or conflicts.

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CONTRACTS WITH MEDICARE ADMINISTRATIVE CONTRACTORS

SEC. 1874A. (a) AUTHORITY.—

(1) AUTHORITY TO ENTER INTO CONTRACTS.—The Secretary may enter into contracts with any eligible entity to serve as a medicare administrative contractor with respect to the performance of any or all of the functions described in paragraph (4) or parts of those functions (or, to the extent provided in a contract, to secure performance thereof by other entities).

(2) ELIGIBILITY OF ENTITIES.—An entity is eligible to enter into a contract with respect to the performance of a particular function described in paragraph (4) only if—

(A) the entity has demonstrated capability to carry out such function;

(B) the entity complies with such conflict of interest standards as are generally applicable to Federal acquisition and procurement;

(C) the entity has sufficient assets to financially support the performance of such function; and

(D) the entity meets such other requirements as the Secretary may impose.

(3) MEDICARE ADMINISTRATIVE CONTRACTOR DEFINED.—For purposes of this title and title XI—

(A) IN GENERAL.—The term "medicare administrative contractor" means an agency, organization, or other person with a contract under this section.

(B) APPROPRIATE MEDICARE ADMINISTRATIVE CONTRACTOR.—With respect to the performance of a particular function in relation to an individual entitled to benefits under part A or enrolled under part B, or both, a specific provider of services or supplier (or class of such providers of services or suppliers), the "appropriate" medicare administrative contractor is the medicare administrative contractor that has a contract under this section with respect to the performance of that function in relation to that individual, provider of services or supplier or class of provider of services or supplier.

(4) FUNCTIONS DESCRIBED.—The functions referred to in paragraphs (1) and (2) are payment functions, provider services functions, and functions relating to services furnished to individuals entitled to benefits under part A or enrolled under part B, or both, as follows:

(A) DETERMINATION OF PAYMENT AMOUNTS.—Determining (subject to the provisions of section 1878 and to such review by the Secretary as may be provided for by the contracts) the amount of the payments required pursuant to this title to be made to providers of services, suppliers and individuals.

(B) MAKING PAYMENTS.—Making payments described in subparagraph (A) (including receipt, disbursement, and accounting for funds in making such payments).

(C) BENEFICIARY EDUCATION AND ASSISTANCE.—Providing education and outreach to individuals entitled to benefits under part A or enrolled under part B, or both, and providing assistance to those individuals with specific issues, concerns or problems.

(D) PROVIDER CONSULTATIVE SERVICES.—Providing consultative services to institutions, agencies, and other persons to enable them to establish and maintain fiscal records necessary for purposes of this title and otherwise to qualify as providers of services or suppliers.

(E) COMMUNICATION WITH PROVIDERS.—Communicating to providers of services and suppliers any information or instructions furnished to the medicare administrative contractor by the Secretary, and facilitating communication between such providers and suppliers and the Secretary.

(F) PROVIDER EDUCATION AND TECHNICAL ASSISTANCE.—Performing the functions relating to provider education, training, and technical assistance.

(G) ADDITIONAL FUNCTIONS.—Performing such other functions as are necessary to carry out the purposes of this title.

(5) RELATIONSHIP TO MIP CONTRACTS.—

(A) NONDUPLICATION OF DUTIES.—In entering into contracts under this section, the Secretary shall assure that functions of medicare administrative contractors in carrying out activities under parts A and B do not duplicate activities carried out under the Medicare Integrity Program under section 1893. The previous sentence shall not apply with respect to the activity described in section 1893(b)(5) (relating to prior authorization of certain items of durable medical equipment under section 1834(a)(15)).

(B) CONSTRUCTION.—An entity shall not be treated as a medicare administrative contractor merely by reason of having entered into a contract with the Secretary under section 1893.

(6) APPLICATION OF FEDERAL ACQUISITION REGULATION.—Except to the extent inconsistent with a specific requirement of this title, the Federal Acquisition Regulation applies to contracts under this title.

(b) CONTRACTING REQUIREMENTS.—

(1) USE OF COMPETITIVE PROCEDURES.—

(A) IN GENERAL.—Except as provided in laws with general applicability to Federal acquisition and procurement or in subparagraph (B), the Secretary shall use competitive procedures when entering into contracts with medicare administrative contractors under this section, taking into account performance quality as well as price and other factors.

(B) RENEWAL OF CONTRACTS.—The Secretary may renew a contract with a medicare administrative contractor under this section from term to term without regard to section 5 of title 41, United States Code, or any other provision of law requiring competition, if the medicare administrative contractor has met or exceeded the performance requirements applicable with respect to the contract and contractor, except that the Secretary shall provide for the application of competitive procedures under such a contract not less frequently than once every five years.

(C) TRANSFER OF FUNCTIONS.—The Secretary may transfer functions among medicare administrative contractors consistent with the provisions of this paragraph. The Secretary shall ensure that performance quality is considered in such transfers. The Secretary shall provide public notice (whether in the Federal Register or otherwise) of any such transfer (including a description of the functions so transferred, a description of the providers of services and suppliers affected by such transfer, and contact information for the contractors involved).

(D) INCENTIVES FOR QUALITY.—The Secretary shall provide incentives for medicare administrative contractors to provide quality service and to promote efficiency.

(2) COMPLIANCE WITH REQUIREMENTS.—No contract under this section shall be entered into with any medicare administrative contractor unless the Secretary finds that such medicare administrative contractor will perform its obligations under the contract efficiently and effectively and will meet such requirements as to financial responsibility, legal authority, quality of services provided, and other matters as the Secretary finds pertinent.

(3) PERFORMANCE REQUIREMENTS.—

(A) DEVELOPMENT OF SPECIFIC PERFORMANCE REQUIREMENTS.—In developing contract performance requirements, the Secretary shall develop performance requirements applicable to functions described in subsection (a)(4).

(B) CONSULTATION.— In developing such requirements, the Secretary may consult with providers of services and suppliers, organizations representing individuals entitled to benefits under part A or enrolled under part B, or both, and organizations and agencies performing functions necessary to carry out the purposes of this section with respect to such performance requirements.

(C) INCLUSION IN CONTRACTS.—All contractor performance requirements shall be set forth in the contract between the Secretary and the appropriate medicare administrative contractor. Such performance requirements—

(i) shall reflect the performance requirements developed under subparagraph (A), but may include additional performance requirements;

(ii) shall be used for evaluating contractor performance under the contract; and

(iii) shall be consistent with the written statement of work provided under the contract.

(4) INFORMATION REQUIREMENTS.—The Secretary shall not enter into a contract with a medicare administrative contractor under this section unless the contractor agrees—

(A) to furnish to the Secretary such timely information and reports as the Secretary may find necessary in performing his functions under this title; and

(B) to maintain such records and afford such access thereto as the Secretary finds necessary to assure the correctness and verification of the information and reports under subparagraph (A) and otherwise to carry out the purposes of this title.

(5) SURETY BOND.—A contract with a medicare administrative contractor under this section may require the medicare administrative contractor, and any of its officers or employees certifying payments or disbursing funds pursuant to the contract, or otherwise participating in carrying out the contract, to give surety bond to the United States in such amount as the Secretary may deem appropriate.

(c) TERMS AND CONDITIONS.—

(1) IN GENERAL.—A contract with any medicare administrative contractor under this section may contain such terms and

conditions as the Secretary finds necessary or appropriate and may provide for advances of funds to the medicare administrative contractor for the making of payments by it under subsection (a)(4)(B).

(2) PROHIBITION ON MANDATES FOR CERTAIN DATA COLLECTION.—The Secretary may not require, as a condition of entering into, or renewing, a contract under this section, that the medicare administrative contractor match data obtained other than in its activities under this title with data used in the administration of this title for purposes of identifying situations in which the provisions of section 1862(b) may apply.

(d) LIMITATION ON LIABILITY OF MEDICARE ADMINISTRATIVE CONTRACTORS AND CERTAIN OFFICERS.—

(1) CERTIFYING OFFICER.—No individual designated pursuant to a contract under this section as a certifying officer shall, in the absence of the reckless disregard of the individual's obligations or the intent by that individual to defraud the United States, be liable with respect to any payments certified by the individual under this section.

(2) DISBURSING OFFICER.—No disbursing officer shall, in the absence of the reckless disregard of the officer's obligations or the intent by that officer to defraud the United States, be liable with respect to any payment by such officer under this section if it was based upon an authorization (which meets the applicable requirements for such internal controls established by the Comptroller General) of a certifying officer designated as provided in paragraph (1) of this subsection.

(3) LIABILITY OF MEDICARE ADMINISTRATIVE CONTRACTOR.—

(A) IN GENERAL.—No medicare administrative contractor shall be liable to the United States for a payment by a certifying or disbursing officer unless, in connection with such payment, the medicare administrative contractor acted with reckless disregard of its obligations under its medicare administrative contract or with intent to defraud the United States.

(B) RELATIONSHIP TO FALSE CLAIMS ACT.—Nothing in this subsection shall be construed to limit liability for conduct that would constitute a violation of sections 3729 through 3731 of title 31, United States Code (commonly known as the "False Claims Act").

(4) INDEMNIFICATION BY SECRETARY.—

(A) IN GENERAL.—Subject to subparagraphs (B) and (D), in the case of a medicare administrative contractor (or a person who is a director, officer, or employee of such a contractor or who is engaged by the contractor to participate directly in the claims administration process) who is made a party to any judicial or administrative proceeding arising from or relating directly to the claims administration process under this title, the Secretary may, to the extent the Secretary determines to be appropriate and as specified in the contract with the contractor, indemnify the contractor and such persons.

(B) CONDITIONS.—The Secretary may not provide indemnification under subparagraph (A) insofar as the liability for such costs arises directly from conduct that is determined by the judicial proceeding or by the Secretary to be

criminal in nature, fraudulent, or grossly negligent. If indemnification is provided by the Secretary with respect to a contractor before a determination that such costs arose directly from such conduct, the contractor shall reimburse the Secretary for costs of indemnification.

(C) SCOPE OF INDEMNIFICATION.—Indemnification by the Secretary under subparagraph (A) may include payment of judgments, settlements (subject to subparagraph (D)), awards, and costs (including reasonable legal expenses).

(D) WRITTEN APPROVAL FOR SETTLEMENTS.—A contractor or other person described in subparagraph (A) may not propose to negotiate a settlement or compromise of a proceeding described in such subparagraph without the prior written approval of the Secretary to negotiate such settlement or compromise. Any indemnification under subparagraph (A) with respect to amounts paid under a settlement or compromise of a proceeding described in such subparagraph are conditioned upon prior written approval by the Secretary of the final settlement or compromise.

(E) CONSTRUCTION.—Nothing in this paragraph shall be construed—

(i) to change any common law immunity that may be available to a medicare administrative contractor or person described in subparagraph (A); or

(ii) to permit the payment of costs not otherwise allowable, reasonable, or allocable under the Federal Acquisition Regulations.

(e) REQUIREMENTS FOR INFORMATION SECURITY.—

(1) DEVELOPMENT OF INFORMATION SECURITY PROGRAM.—A medicare administrative contractor that performs the functions referred to in subparagraphs (A) and (B) of subsection (a)(4) (relating to determining and making payments) shall implement a contractor-wide information security program to provide information security for the operation and assets of the contractor with respect to such functions under this title. An information security program under this paragraph shall meet the requirements for information security programs imposed on Federal agencies under paragraphs (1) through (8) of section 3544(b) of title 44, United States Code (other than requirements under paragraphs (2)(D)(i), (5)(A), and (5)(B) of such section).

(2) INDEPENDENT AUDITS.—

(A) PERFORMANCE OF ANNUAL EVALUATIONS.—Each year a medicare administrative contractor that performs the functions referred to in subparagraphs (A) and (B) of subsection (a)(4) (relating to determining and making payments) shall undergo an evaluation of the information security of the contractor with respect to such functions under this title. The evaluation shall—

(i) be performed by an entity that meets such requirements for independence as the Inspector General of the Department of Health and Human Services may establish; and

(ii) test the effectiveness of information security policies, procedures, and practices of a representative subset of the contractor's information systems (as defined

in section 3502(8) of title 44, United States Code) relating to such functions under this title and an assessment of compliance with the requirements of this subsection and related information security policies, procedures, standards and guidelines, including policies and procedures as may be prescribed by the Director of the Office of Management and Budget and applicable information security standards promulgated under section 11331 of title 40, United States Code.

(B) DEADLINE FOR INITIAL EVALUATION.—

(i) NEW CONTRACTORS.—In the case of a medicare administrative contractor covered by this subsection that has not previously performed the functions referred to in subparagraphs (A) and (B) of subsection (a)(4) (relating to determining and making payments) as a fiscal intermediary or carrier under section 1816 or 1842, the first independent evaluation conducted pursuant subparagraph (A) shall be completed prior to commencing such functions.

(ii) OTHER CONTRACTORS.—In the case of a medicare administrative contractor covered by this subsection that is not described in clause (i), the first independent evaluation conducted pursuant subparagraph (A) shall be completed within 1 year after the date the contractor commences functions referred to in clause (i) under this section.

(C) REPORTS ON EVALUATIONS.—

(i) TO THE DEPARTMENT OF HEALTH AND HUMAN SERVICES.—The results of independent evaluations under subparagraph (A) shall be submitted promptly to the Inspector General of the Department of Health and Human Services and to the Secretary.

(ii) TO CONGRESS.—The Inspector General of Department of Health and Human Services shall submit to Congress annual reports on the results of such evaluations, including assessments of the scope and sufficiency of such evaluations.

(iii) AGENCY REPORTING.—The Secretary shall address the results of such evaluations in reports required under section 3544(c) of title 44, United States Code.

(f) INCENTIVES TO IMPROVE CONTRACTOR PERFORMANCE IN PROVIDER EDUCATION AND OUTREACH.—The Secretary shall use specific claims payment error rates or similar methodology of medicare administrative contractors in the processing or reviewing of medicare claims in order to give such contractors an incentive to implement effective education and outreach programs for providers of services and suppliers.

(g) COMMUNICATIONS WITH BENEFICIARIES, PROVIDERS OF SERVICES AND SUPPLIERS.—

(1) COMMUNICATION STRATEGY.—The Secretary shall develop a strategy for communications with individuals entitled to benefits under part A or enrolled under part B, or both, and with providers of services and suppliers under this title.

(2) RESPONSE TO WRITTEN INQUIRIES.—Each medicare administrative contractor shall, for those providers of services and

suppliers which submit claims to the contractor for claims processing and for those individuals entitled to benefits under part A or enrolled under part B, or both, with respect to whom claims are submitted for claims processing, provide general written responses (which may be through electronic transmission) in a clear, concise, and accurate manner to inquiries of providers of services, suppliers and individuals entitled to benefits under part A or enrolled under part B, or both, concerning the programs under this title within 45 business days of the date of receipt of such inquiries.

(3) RESPONSE TO TOLL-FREE LINES.—The Secretary shall ensure that each medicare administrative contractor shall provide, for those providers of services and suppliers which submit claims to the contractor for claims processing and for those individuals entitled to benefits under part A or enrolled under part B, or both, with respect to whom claims are submitted for claims processing, a toll-free telephone number at which such individuals, providers of services and suppliers may obtain information regarding billing, coding, claims, coverage, and other appropriate information under this title.

(4) MONITORING OF CONTRACTOR RESPONSES.—

(A) IN GENERAL.—Each medicare administrative contractor shall, consistent with standards developed by the Secretary under subparagraph (B)—

(i) maintain a system for identifying who provides the information referred to in paragraphs (2) and (3); and

(ii) monitor the accuracy, consistency, and timeliness of the information so provided.

(B) DEVELOPMENT OF STANDARDS.—

(i) IN GENERAL.—The Secretary shall establish and make public standards to monitor the accuracy, consistency, and timeliness of the information provided in response to written and telephone inquiries under this subsection. Such standards shall be consistent with the performance requirements established under subsection (b)(3).

(ii) EVALUATION.—In conducting evaluations of individual medicare administrative contractors, the Secretary shall take into account the results of the monitoring conducted under subparagraph (A) taking into account as performance requirements the standards established under clause (i). The Secretary shall, in consultation with organizations representing providers of services, suppliers, and individuals entitled to benefits under part A or enrolled under part B, or both, establish standards relating to the accuracy, consistency, and timeliness of the information so provided.

(C) DIRECT MONITORING.—Nothing in this paragraph shall be construed as preventing the Secretary from directly monitoring the accuracy, consistency, and timeliness of the information so provided.

(h) CONDUCT OF PREPAYMENT REVIEW.—

(1) CONDUCT OF RANDOM PREPAYMENT REVIEW.—

(A) IN GENERAL.—A medicare administrative contractor may conduct random prepayment review only to develop a contractor-wide or program-wide claims payment error rates or under such additional circumstances as may be provided under regulations, developed in consultation with providers of services and suppliers.

(B) USE OF STANDARD PROTOCOLS WHEN CONDUCTING PREPAYMENT REVIEWS.—When a medicare administrative contractor conducts a random prepayment review, the contractor may conduct such review only in accordance with a standard protocol for random prepayment audits developed by the Secretary.

(C) CONSTRUCTION.—Nothing in this paragraph shall be construed as preventing the denial of payments for claims actually reviewed under a random prepayment review.

(D) RANDOM PREPAYMENT REVIEW.—For purposes of this subsection, the term "random prepayment review" means a demand for the production of records or documentation absent cause with respect to a claim.

(2) LIMITATIONS ON NON-RANDOM PREPAYMENT REVIEW.—

(A) LIMITATIONS ON INITIATION OF NON-RANDOM PREPAYMENT REVIEW.—A medicare administrative contractor may not initiate non-random prepayment review of a provider of services or supplier based on the initial identification by that provider of services or supplier of an improper billing practice unless there is a likelihood of sustained or high level of payment error (as defined in subsection (i)(3)(A)).

(B) TERMINATION OF NON-RANDOM PREPAYMENT REVIEW.—The Secretary shall issue regulations relating to the termination, including termination dates, of non-random prepayment review. Such regulations may vary such a termination date based upon the differences in the circumstances triggering prepayment review.

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PROVIDER EDUCATION AND TECHNICAL ASSISTANCE

SEC. 1889. (a) COORDINATION OF EDUCATION FUNDING.—The Secretary shall coordinate the educational activities provided through medicare contractors (as defined in subsection (g), including under section 1893) in order to maximize the effectiveness of Federal education efforts for providers of services and suppliers.

(b) ENHANCED EDUCATION AND TRAINING.—

(1) ADDITIONAL RESOURCES.—There are authorized to be appropriated to the Secretary (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) $25,000,000 for each of fiscal years 2005 and 2006 and such sums as may be necessary for succeeding fiscal years.

(2) USE.—The funds made available under paragraph (1) shall be used to increase the conduct by medicare contractors of education and training of providers of services and suppliers regarding billing, coding, and other appropriate items and may also be used to improve the accuracy, consistency, and timeliness of contractor responses.

(c) TAILORING EDUCATION AND TRAINING ACTIVITIES FOR SMALL PROVIDERS OR SUPPLIERS.—

(1) IN GENERAL.—Insofar as a medicare contractor conducts education and training activities, it shall tailor such activities to meet the special needs of small providers of services or suppliers (as defined in paragraph (2)).

(2) SMALL PROVIDER OF SERVICES OR SUPPLIER.—In this subsection, the term "small provider of services or supplier" means—

(A) a provider of services with fewer than 25 full-time-equivalent employees; or

(B) a supplier with fewer than 10 full-time-equivalent employees.

(d) INTERNET SITES; FAQS.—The Secretary, and each medicare contractor insofar as it provides services (including claims processing) for providers of services or suppliers, shall maintain an Internet site which—

(1) provides answers in an easily accessible format to frequently asked questions, and

(2) includes other published materials of the contractor,

that relate to providers of services and suppliers under the programs under this title (and title XI insofar as it relates to such programs).

(e) ENCOURAGEMENT OF PARTICIPATION IN EDUCATION PROGRAM ACTIVITIES.—A medicare contractor may not use a record of attendance at (or failure to attend) educational activities or other information gathered during an educational program conducted under this section or otherwise by the Secretary to select or track providers of services or suppliers for the purpose of conducting any type of audit or prepayment review.

(f) CONSTRUCTION.—Nothing in this section or section 1893(g) shall be construed as providing for disclosure by a medicare contractor of information that would compromise pending law enforcement activities or reveal findings of law enforcement-related audits.

(g) DEFINITIONS.—For purposes of this section, the term "medicare contractor" includes the following:

(1) A medicare administrative contractor with a contract under section 1874A, including a fiscal intermediary with a contract under section 1816 and a carrier with a contract under section 1842.

(2) An eligible entity with a contract under section 1893.

Such term does not include, with respect to activities of a specific provider of services or supplier an entity that has no authority under this title or title IX with respect to such activities and such provider of services or supplier.

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MEDICARE INTEGRITY PROGRAM

SEC. 1893. (a) * * *

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(f) RECOVERY OF OVERPAYMENTS.—

(1) USE OF REPAYMENT PLANS.—

(A) IN GENERAL.—If the repayment, within 30 days by a provider of services or supplier, of an overpayment under

this title would constitute a hardship (as defined in subparagraph (B)), subject to subparagraph (C), upon request of the provider of services or supplier the Secretary shall enter into a plan with the provider of services or supplier for the repayment (through offset or otherwise) of such overpayment over a period of at least 6 months but not longer than 3 years (or not longer than 5 years in the case of extreme hardship, as determined by the Secretary). Interest shall accrue on the balance through the period of repayment. Such plan shall meet terms and conditions determined to be appropriate by the Secretary.

(B) HARDSHIP.—

(i) IN GENERAL.—For purposes of subparagraph (A), the repayment of an overpayment (or overpayments) within 30 days is deemed to constitute a hardship if—

(I) in the case of a provider of services that files cost reports, the aggregate amount of the overpayments exceeds 10 percent of the amount paid under this title to the provider of services for the cost reporting period covered by the most recently submitted cost report; or

(II) in the case of another provider of services or supplier, the aggregate amount of the overpayments exceeds 10 percent of the amount paid under this title to the provider of services or supplier for the previous calendar year.

(ii) RULE OF APPLICATION.—The Secretary shall establish rules for the application of this subparagraph in the case of a provider of services or supplier that was not paid under this title during the previous year or was paid under this title only during a portion of that year.

(iii) TREATMENT OF PREVIOUS OVERPAYMENTS.—If a provider of services or supplier has entered into a repayment plan under subparagraph (A) with respect to a specific overpayment amount, such payment amount under the repayment plan shall not be taken into account under clause (i) with respect to subsequent overpayment amounts.

(C) EXCEPTIONS.—Subparagraph (A) shall not apply if—

(i) the Secretary has reason to suspect that the provider of services or supplier may file for bankruptcy or otherwise cease to do business or discontinue participation in the program under this title; or

(ii) there is an indication of fraud or abuse committed against the program.

(D) IMMEDIATE COLLECTION IF VIOLATION OF REPAYMENT PLAN.—If a provider of services or supplier fails to make a payment in accordance with a repayment plan under this paragraph, the Secretary may immediately seek to offset or otherwise recover the total balance outstanding (including applicable interest) under the repayment plan.

(E) RELATION TO NO FAULT PROVISION.—Nothing in this paragraph shall be construed as affecting the application of

section 1870(c) (relating to no adjustment in the cases of certain overpayments).

(2) LIMITATION ON RECOUPMENT.—

(A) IN GENERAL.—In the case of a provider of services or supplier that is determined to have received an overpayment under this title and that seeks a reconsideration by a qualified independent contractor on such determination under section 1869(b)(1), the Secretary may not take any action (or authorize any other person, including any medicare contractor, as defined in subparagraph (C)) to recoup the overpayment until the date the decision on the reconsideration has been rendered. If the provisions of section 1869(b)(1) (providing for such a reconsideration by a qualified independent contractor) are not in effect, in applying the previous sentence any reference to such a reconsideration shall be treated as a reference to a redetermination by the fiscal intermediary or carrier involved.

(B) COLLECTION WITH INTEREST.—Insofar as the determination on such appeal is against the provider of services or supplier, interest on the overpayment shall accrue on and after the date of the original notice of overpayment. Insofar as such determination against the provider of services or supplier is later reversed, the Secretary shall provide for repayment of the amount recouped plus interest at the same rate as would apply under the previous sentence for the period in which the amount was recouped.

(C) MEDICARE CONTRACTOR DEFINED.—For purposes of this subsection, the term "medicare contractor" has the meaning given such term in section 1889(g).

(3) LIMITATION ON USE OF EXTRAPOLATION.—A medicare contractor may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise unless—

(A) there is a sustained or high level of payment error (as defined by the Secretary by regulation); or

(B) documented educational intervention has failed to correct the payment error (as determined by the Secretary).

(4) PROVISION OF SUPPORTING DOCUMENTATION.—In the case of a provider of services or supplier with respect to which amounts were previously overpaid, a medicare contractor may request the periodic production of records or supporting documentation for a limited sample of submitted claims to ensure that the previous practice is not continuing.

(5) CONSENT SETTLEMENT REFORMS.—

(A) IN GENERAL.—The Secretary may use a consent settlement (as defined in subparagraph (D)) to settle a projected overpayment.

(B) OPPORTUNITY TO SUBMIT ADDITIONAL INFORMATION BEFORE CONSENT SETTLEMENT OFFER.—Before offering a provider of services or supplier a consent settlement, the Secretary shall—

(i) communicate to the provider of services or supplier—

(I) that, based on a review of the medical records requested by the Secretary, a preliminary evalua-

tion of those records indicates that there would be an overpayment;

(II) the nature of the problems identified in such evaluation; and

(III) the steps that the provider of services or supplier should take to address the problems; and

(ii) provide for a 45-day period during which the provider of services or supplier may furnish additional information concerning the medical records for the claims that had been reviewed.

(C) CONSENT SETTLEMENT OFFER.—The Secretary shall review any additional information furnished by the provider of services or supplier under subparagraph (B)(ii). Taking into consideration such information, the Secretary shall determine if there still appears to be an overpayment. If so, the Secretary—

(i) shall provide notice of such determination to the provider of services or supplier, including an explanation of the reason for such determination; and

(ii) in order to resolve the overpayment, may offer the provider of services or supplier—

(I) the opportunity for a statistically valid random sample; or

(II) a consent settlement.

The opportunity provided under clause (ii)(I) does not waive any appeal rights with respect to the alleged overpayment involved.

(D) CONSENT SETTLEMENT DEFINED.—For purposes of this paragraph, the term "consent settlement" means an agreement between the Secretary and a provider of services or supplier whereby both parties agree to settle a projected overpayment based on less than a statistically valid sample of claims and the provider of services or supplier agrees not to appeal the claims involved.

(6) NOTICE OF OVER-UTILIZATION OF CODES.—The Secretary shall establish, in consultation with organizations representing the classes of providers of services and suppliers, a process under which the Secretary provides for notice to classes of providers of services and suppliers served by the contractor in cases in which the contractor has identified that particular billing codes may be overutilized by that class of providers of services or suppliers under the programs under this title (or provisions of title XI insofar as they relate to such programs).

(7) PAYMENT AUDITS.—

(A) WRITTEN NOTICE FOR POST-PAYMENT AUDITS.—Subject to subparagraph (C), if a medicare contractor decides to conduct a post-payment audit of a provider of services or supplier under this title, the contractor shall provide the provider of services or supplier with written notice (which may be in electronic form) of the intent to conduct such an audit.

(B) EXPLANATION OF FINDINGS FOR ALL AUDITS.—Subject to subparagraph (C), if a medicare contractor audits a provider of services or supplier under this title, the contractor shall—

(i) give the provider of services or supplier a full review and explanation of the findings of the audit in a manner that is understandable to the provider of services or supplier and permits the development of an appropriate corrective action plan;

(ii) inform the provider of services or supplier of the appeal rights under this title as well as consent settlement options (which are at the discretion of the Secretary);

(iii) give the provider of services or supplier an opportunity to provide additional information to the contractor; and

(iv) take into account information provided, on a timely basis, by the provider of services or supplier under clause (iii).

(C) EXCEPTION.—Subparagraphs (A) and (B) shall not apply if the provision of notice or findings would compromise pending law enforcement activities, whether civil or criminal, or reveal findings of law enforcement-related audits.

(8) STANDARD METHODOLOGY FOR PROBE SAMPLING.—The Secretary shall establish a standard methodology for medicare contractors to use in selecting a sample of claims for review in the case of an abnormal billing pattern.

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VII. DISSENTING VIEWS

For two years, members of this Committee have worked on a bipartisan basis to write this legislation. Democratic and, until now, Republican members have faithfully followed the ground rules and operating principles established by the Chairmen of the Committee and the Health Subcommittee with respect to the creation and consideration of the Medicare Regulatory and Contracting Reform Act. This common understanding helped the Committee set aside partisan differences and unified member support on both sides of the aisle for this targeted bill. Such consensus on legislation affecting Medicare has been virtually non-existent in the Committee in recent years.

We stongly support the legislation as presented in the Chairman's mark. Our vote to oppose reporting of the legislation was primarily a reflection of our protest of the abandonment of a process that had served both the Committee and the issues under consideration well.

The addition of controversial amendments in the Committee undercut the process and seriously undermined the trust and goodwill that had accumulated among members around the development and advancement of this particular legislation.

We do not normally like to be put in a position where amendments are discouraged, as it undermines the free and full debate that should be the hallmark of the democratic process. However, in this case, it was well-understood to be a bipartisan directive. When this legislation was before the Committee in the 107th Congress, the Chairman had stipulated that amendments could not be offered.

Given an opportunity for full and fair debate regarding the amendments that were offered, some of us might have been able to find bipartisan agreement on these issues, as has been done on other provisions in the mark. That said, many of us are concerned about the issues raised by the beneficiary organizations that opposed the amendments. Those organizations, whose letters have been inserted elsewhere in the Record, include the AARP and the National Citizens' Coalition for Nursing Home Reform. Testimony from the Center for Medicare Advocacy at the Health Subcommittee hearing on H.R. 810 also reflects concerns about both of the proposals that were offered as amendments.

In addition, there was an explicit prior agreement between the Chairman and Ranking Member of the Health Subcommittee that the OASIS issue dealt with in the Johnson amendment would instead be reflected in a General Accounting Office study. Furthermore, the Camp amendment to rollback penalties for nursing homes with serious deficiencies flies in the face of the need to increase oversight and enforcement of quality standards in the nursing homes.

Members and staff have spent countless hours meeting with various affected interest groups, the Administration, and colleagues on the Energy and Commerce Committee over the past two years. The Chairman's Mark consisted of policies that were broadly supported on both sides of the aisle. We hope that the legislation brought to the floor reflects that agreement.

PETE STARK.
STEPHANIE TUBBS JONES.
JERRY KLECZKA.
LLOYD DOGGETT.
WILLIAM J. JEFFERSON.
BEN CARDIN.
RICHARD E. NEAL.
EARL POMEROY.
CHARLES B. RANGEL.
SANDER LEVIN.
XAVIER BECERRA.
MICHAEL R. MCNULTY.
MAX SANDLIN.
JOHN LEWIS.
JIM MCDERMOTT.
JOHN S. TANNER.

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